DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

21 CFR Ch. I

42 CFR Chs. I-V

45 CFR Subtitle A; Subtitle B, Chs. II, III, and XIII

Regulatory Agenda

AGENCY: Office of the Secretary, HHS.

ACTION: Semiannual Regulatory Agenda.

SUMMARY: The Regulatory Flexibility Act of 1980 and Executive Order (EO) 12866 requires the semi-annual issuance of an inventory of rulemaking actions under development throughout the Department with a view to offering summarized information about forthcoming regulatory actions for public review.

FOR FURTHER INFORMATION CONTACT: Dawn L. Smalls, Executive Secretary, Department of Health and Human Services, Washington, DC 20201.

SUPPLEMENTARY INFORMATION: The information provided in the Agenda presents a forecast of the rulemaking activities that the Department of Health and Human Services (HHS) expects to undertake in the foreseeable future. Rulemakings are grouped according to pre-rulemaking actions, proposed rules, final rules, long-term actions, and rulemaking actions completed since the spring 2009 Agenda was published.

Please note that the rulemaking abstracts included in this issue of the **Federal Register** relate only to those prospective rulemakings that are likely to have a significant economic impact on a substantial number of small entities as required by the Regulatory Flexibility Act of 1980. Also available in this issue of the **Register** is the Department's submission to the fiscal year 2010 Regulatory Plan as required under Executive Order 12866.

The purpose of the Agenda is to encourage more effective public participation in the regulatory process, and HHS invites all interested members of the public to comment on the rulemaking actions included in this issuance of the Agenda. The complete regulatory agenda of the Department is accessible online at www.reginfo.gov in an interactive format that offers users enhanced capabilities to obtain information from the Agenda's database.

Dated: October 9, 2009.

NAME: Dawn L. Smalls,
Executive Secretary,
Department of Health and Human Services.

The 231 Regulatory Agendas

Health Resources and Services Administration - Proposed Rule

Title	Regulation Identifier Number
Add Vascularized Composite Allografts to the Definition of Organs Covered by the Rule Governing the Operation of the Organ Procurement and Transplantation Network (OPTN)	0906-AA73
National Vaccine Injury Compensation Program: Separate Category for Hepatitis A, Influenza, Meningococcal, Human Papillomavirus Vaccines	0906-AA74
Health Center Federal Tort Claims Act (FTCA) Medical Malpractice Program Regulations--Clarification of FTCA Coverage for Services Provided to Non-Health Center Patients	0906-AA77

Health Resources and Services Administration - Final Rule

Title	Regulation Identifier Number
National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Reporting Adverse and Negative Actions	0906-AA57

Health Resources and Services Administration - Long-term Action

Title	Regulation Identifier Number
Designation of Medically Underserved Populations and Health Professional Shortage Areas	0906-AA44
Health Center Program Regulations--Consolidation With Migrant Health Center Program Regulations and Extension of Applicability to Health Care for the Homeless And Public Housing Primary Care Health	0906-AA76

Health Resources and Services Administration - Completed Action

Title	Regulation Identifier Number
Federal Tort Claims Act (FTCA) Coverage of Certain Grantees and Individuals: Covered Acts and Omissions—Continuing Medical Education	0906-AA78

Food and Drug Administration - PreRule

Title	Regulation Identifier Number
Food Labeling: Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution	0910-AG06
Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures	0910-AG14
Sterility Requirement for Aqueous-Based Drug Products for Oral Inhalation	0910-AG25
Over-the-Counter Human Drugs; Labeling Requirements	0910-AG34

Food and Drug Administration - Proposed Rule

Title	Regulation Identifier Number
Electronic Submission of Data From Studies Evaluating Human Drugs and Biologics	0910-AC52
Reporting Information Regarding Falsification of Data	0910-AC59
Over-the-Counter (OTC) Drug Review--Cough/Cold (Antihistamine) Products	

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Over-the-Counter (OTC) Drug Review--Poison Treatment Drug Products	0910-AF68
Import Tolerances for Unapproved New Animal Drugs	0910-AF78
Postmarket Safety Reporting for Combination Products	0910-AF82
Laser Products; Amendment to Performance Standard	0910-AF87
Electronic Registration and Listing for Devices	0910-AF88
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Proposed Revisions To Implement Portions of Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and Other Changes	0910-AF97
Animal Food Labeling; Declaration of Certifiable Color Additives	0910-AG02
Conditional Approval of New Animal Drugs for Minor Use and Minor Species	0910-AG07
Animal Feed Ingredient Standards and Definitions	0910-AG08
Pet Food Labeling Requirements	0910-AG09
Process Controls for Animal Feed Ingredients and Mixed Animal Feed	0910-AG10
Pediatric Dosing for Cough, Cold, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph	0910-AG12
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New Animal Drugs: Updating Tolerances for Residues in New Animal Drugs in Food	0910-AG17
Electronic Distribution of Content of Labeling for Human Prescription Drug and Biological Products	0910-AG18
Amendment to the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals	0910-AG20
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Amendments to Regulations on Citizen Petitions, Petitions for Stay of Action, and Submission of Documents to Dockets; Implementation of Section 505(q) of the Federal Food, Drug, and Cosmetic Act	0910-AG26
Direct-to-Consumer Prescription Drug Advertisements: Presentation of the Major Statement in Television and Radio Advertisements in a Clear, Conspicuous, and Neutral Manner	0910-AG27
Animal Drugs, Feeds, and Related Products; Regulation of Carcinogenic Compounds in Food-Producing Animals	0910-AG28
Requirement for Submission of Information on Pediatric Subpopulations That Suffer From a Disease or Condition That a Device Is Intended to Treat, Diagnose, or Cure	0910-AG29
Informed Consent Elements	0910-AG32
Produce Safety Regulation	0910-AG35
Modernization of the Current Food Good Manufacturing Practices Regulation	0910-AG36

Food and Drug Administration - Final Rule

Title	Regulation Identifier Number
Foreign and Domestic Establishment Registration and Listing Requirements for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs	0910-AA49
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Exception From General Requirements for Informed Consent; Request for Comments and Information	0910-AC25
Medical Devices; Anesthesiology Devices; Reclassification of Pressure Regulators for Use With Medical Oxygen and Separate Classification of Oxygen Conserving Devices	0910-AC30
Medical Gas Containers and Closures; Current Good Manufacturing Practice Requirements	0910-AC53
Positron Emission Tomography Drugs; Current Good Manufacturing Practices	0910-AC55
Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation Labeling	0910-AF11

Blood Initiative--Revisions to Labeling Requirements for Blood and Blood Components, Including Source Plasma; and Technical Amendment	0910-AF26
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Over-the-Counter (OTC) Drug Review--Cough/Cold (Combination) Products	0910-AF33
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Food and Drug Administration - Long-term Action

Title	Regulation Identifier Number
Current Good Manufacturing Practice in Manufacturing, Packing, Labeling, or Holding Operations for Dietary Supplements	0910-AB88
Food Labeling: Trans Fatty Acids in Nutrition Labeling: Consumer Research To Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements	0910-AC50
Food Standards: General Principles and Food Standards Modernization	0910-AC54
Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; Revision of Certain Labeling Controls	0910-AF08
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Blood Initiative--Requirements for Human Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use	0910-AF25
Over-the-Counter (OTC) Drug Review--Ophthalmic Products	0910-AF39
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Food and Drug Administration - Completed Action

Title	Regulation Identifier Number
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Prevention of Salmonella Enteritidis in Shell Eggs	0910-AC14
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Classification of Dental Amalgam, Reclassification of Dental Mercury, Designation of Special Controls for Dental Amalgam, Mercury, and Amalgam Alloy	0910-AG21

Centers for Disease Control and Prevention - PreRule

Title	Regulation Identifier Number
Amendments to Powered Air-Purifying Respirator Requirements for Approval of Respiratory Protection Devices	0920-AA16

Centers for Disease Control and Prevention - Proposed Rule

Title	Regulation Identifier Number
Foreign Quarantine Regulations, Proposed Revision of HHS/CDC Animal Importation Regulations	0920-AA14
Amendments to Specifications for Medical Examinations of Underground Coal Miners	0920-AA21
Control of Communicable Diseases: Foreign Quarantine Regulations, Proposed Revision of HHS/CDC Nonhuman Primate Regulations	0920-AA23
Medical Examination of Aliens	0920-AA28
Possessions, Use, and Transfer of Select Agents and Toxins--Pandemic Influenza	0920-AA30
Total Inward Leakage Requirements for Respirators;	0920-AA33

Centers for Disease Control and Prevention - Final Rule

Title	Regulation Identifier Number
Amendments to Quality Assurance and Administrative Provision for Approval of Respiratory Protective Devices	0920-AA04
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Centers for Disease Control and Prevention - Long-term Action

Title	Regulation Identifier

	Number
Amendments to Performance Requirements for Chemical, Biological, Radiological, and Nuclear (CBRN) Approval of Respiratory Protective Devices	0920-AA17
Possession, Use, and Transfer of Select Agents and Toxins (Sars-CoV)	0920-AA31
Possession, Use and Transfer of Select Agents and Toxins	0920-AA32

Centers for Disease Control and Prevention - Completed Action

Title	Regulation Identifier Number
Possession, Use, and Transfer of Select Agents and Toxins	0920-AA24
Medical Examination of Aliens: Removal of HIV Infection as a Communicable Disease of Public Health Significance	0920-AA26

National Institutes of Health - Proposed Rule

Title	Regulation Identifier Number
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National Institutes of Health Construction Grants	0925-AA57

National Institutes of Health - Final Rule

Title	Regulation Identifier Number
Grants for Research Projects	0925-AA42

National Institutes of Health - Completed Action

Title	Regulation Identifier Number
Procedures for Registration of Applicable Clinical Trials in the ClinicalTrials.gov Registry	0925-AA52
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Substance Abuse and Mental Health Services Administration - Final Rule

Title	Regulation Identifier Number
Opioid Drugs in Maintenance or Detoxification Treatment of Opiate Addition	0930-AA14

Substance Abuse and Mental Health Services Administration - Long-term Action

Title	Regulation Identifier Number
Requirements Governing the Use of Seclusion and Restraint in Certain Nonmedical Community-Based Facilities for Children and Youth	0930-AA10

Centers for Medicare & Medicaid Services - Proposed Rule

Title	Regulation Identifier Number
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Revisions to Payment Policies Under the Physician Fee Schedule and Part B for CY 2011 (CMS-1503-P)	0938-AP79
Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and FY 2011 Rates and to the Long-Term Care Hospital PPS and RY 2011 Rates (CMS-1498-P)	0938-AP80
Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2011 (CMS-1504-P)	0938-AP82
Hospice Wage Index for FY 2011 (CMS-1523-P)	0938-AP84
Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2011 (CMS-1338-P)	0938-AP87
Home Health Prospective Payment System Refinements and Rate Update for CY 2011 (CMS-1510-P)	0938-AP88
Prospective Payment System for Inpatient Rehabilitation Facilities for FY 2011 (CMS-1344-P)	0938-AP89

Centers for Medicare & Medicaid Services - Final Rule

Title	Regulation Identifier Number
Revisions to the Appeals Process for Initial Claim Determinations (CMS-4064-F)	0938-AM73
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Revisions to Payment Policies Under the Physician Fee Schedule for CY 2010 (CMS-1413-FC)	0938-AP40
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Children's Health Insurance Program (CHIP); Allotment Methodology and States' Fiscal Year 2009 CHIP Allotments (CMS-2291-F)	0938-AP53
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Final and Preliminary Fiscal Year Disproportionate Share Hospital Payment Allotments and Institutions for Mental Disease Limits (CMS-2300-N)	0938-AP66
Multiple Source Drug Definition Amendment (CMS-2238-F2)	0938-AP67
Part B Monthly Actuarial Rates, Monthly Premium Rates, and Annual Deductible Beginning January 1, 2011 (CMS-8042-N)	0938-AP81
Inpatient Psychiatric Facility Prospective Payment System--Update for Rate Year Beginning July 1, 2010 (RY 2011) (CMS-1424-N)	0938-AP83
Part A Premiums for CY 2011 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (CMS-8041-N)	0938-AP85
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Centers for Medicare & Medicaid Services - Long-term Action

Title	Regulation Identifier Number
Home Health Agency (HHA) Conditions of Participation (CoPs) (CMS-3819-P)	0938-AG81
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Use of Restraints and Seclusion in Residential Treatment Facilities Providing Inpatient Psychiatric Services to Individuals Under Age 21 (CMS-2065-F)	0938-AJ96
Electronic Claims Attachments Standards (CMS-0050-IFC)	0938-AK62
Health Coverage Portability: Tolling Certain Time Periods and Interactions With Family and Medical Leave Act (CMS-2158-F)	0938-AL88

Revisions to the Requirements for Quality Improvement Organizations (CMS-3156-P)	0938-AN73
Payments for Service Provided Without Charge (Free Care) (CMS-2489-P)	0938-AO07
Medical Improvement Eligibility Group and Definition of Work (CMS-2143-P)	0938-AO10
Cytology Proficiency Testing (CMS-2252-F)	0938-AO34
Targeted Case Management (CMS-2237-F)	0938-AO50
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Application of Certain Appeals Provisions to the Medicare Prescription Drug Appeals Process (CMS-4127-F)	0938-AO87
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Requirements for Long-Term Care Facilities: Hospice Services (CMS-3140-P)	0938-AP32
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State Flexibility for Medicaid Benefit Packages (CMS-2232-F4)	0938-AP72
Premiums and Cost Sharing (CMS-2244-FC)	0938-AP73

Centers for Medicare & Medicaid Services - Completed Action

Title	Regulation Identifier Number
Use of Restraints and Seclusion in Medicare and Medicaid Participating Facilities That Provide Inpatient or Residential Care (CMS-2130-P)	0938-AL26
Limitation on Recoupment of Provider and Supplier Overpayments (CMS-6025-F)	0938-AN42
Rehabilitation Services: State Plan Option (CMS-2261-P)	0938-AO81
Medicaid Graduate Medical Education (CMS-2279-F)	0938-AO95
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Genetic Information Nondiscrimination Act of 2008 (CMS-4137-IFC)	0938-AP37
Changes to the Hospital Inpatient and Long-Term Care Prospective Payment System for FY 2010 (CMS-1406-F)	0938-AP39
Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for CY 2010 (CMS-8037-N)	0938-AP42
Part A Premiums for CY 2010 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (CMS-8038-N)	0938-AP43
Hospice Wage Index for FY 2010 (CMS-1420-F)	0938-AP45
Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2010 (CMS-1410-F)	0938-AP46
Part B Monthly Actuarial Rates, Monthly Premium Rates, and Annual Deductible Beginning January 1, 2010 (CMS-8039-N)	0938-AP48
Inpatient Psychiatric Facility Prospective Payment System--Update for Rate Year Beginning July 1, 2009 (RY 2010) (CMS-1495-NC)	0938-AP50
Revisions to the Medicare Advantage and Prescription Drug Programs (CMS-4138-F)	0938-AP52
Home Health Prospective Payment System and Rate Update for CY 2010 (CMS-1560-F)	0938-AP55
Prospective Payment System for Inpatient Rehabilitation Facilities for FY 2010 (CMS-1538-F)	0938-AP56
Recognition of NAIC Model Standards for Regulation of Medicare Supplemental Insurance (CMS-4139-N)	0938-AP62
Health Care-Related Taxes (CMS-2275-F2)	0938-AP74
Rescission of School-Based Services Final Rule, Outpatient Services Definition Final Rule, and Partial Rescission of Case Management Services Interm Final Rule (CMS-2287-F2)	0938-AP75
Revisions to FY 2009 Medicare Severity--Long-Term Care--Diagnosis-Related Group Weights (CMS-1337-IFC)	0938-AP76

Office of Public Health and Science - Long-term Action

Title	Regulation Identifier Number
Public Health Service Standards for the Protection of Research Misconduct Whistleblowers	0940-AA01

Administration for Children and Families - Proposed Rule

Title	Regulation Identifier Number
Revised Head Start Performance Standards, Target Population and Conversion	0970-AC36
Interim Assistance for Trafficking Victims Under the Trafficking Victims Reauthorization Act of 2008	0970-AC39
Implementation of the Unaccompanied Alien Children (UAC) Provisions of the Trafficking Victims Reauthorization Act of 2008	0970-AC42
Performance Standards for Runaway and Homeless Youth Grantees	0970-AC43
Recompetition of Head Start Grantees	0970-AC44
Safeguarding Child Support Information	0970-AC45

Administration for Children and Families - Final Rule

Title	Regulation Identifier Number
Limitation on Use of Funds Made Available To Monitor and Combat Trafficking In Persons	0970-AC28
Computerized Tribal IV-D System and Office Automation	0970-AC32
Advance Planning Document Reform	0970-AC33
Intergovernmental Child Support Enforcement	0970-AC37
Use of TANF Funds Carried Over From Prior Year	0970-AC40
Tribal Child Welfare	0970-AC41

Administration for Children and Families - Completed Action

Title	Regulation Identifier Number
Target Population and Conversion	0970-AC35

Office of the Secretary - Proposed Rule

Title	Regulation Identifier Number
Revisions to Regulations Addressing the OIG's Authority To Impose Civil Money Penalties and Assessments	0991-AB03
Revisions to the Office of Inspector General's (OIG) Exclusion Authorities	0991-AB33
Revisions to OIG Regulations Governing State Medicaid Fraud Control Units	0991-AB41
Travel Reimbursement for Medicare Hearings Before Administrative Law Judges (ALJs) of the Office of Medicare Hearings and Appeals	0991-AB45
Principles for Determining Costs at Hospitals Under Federal Grants, Contracts, and Cooperative Agreements	0991-AB51
Rescission of Interest Prohibition in the Principles for Determining Costs at Hospitals Under Federal Grants, Contracts, and Cooperative Agreements	0991-AB52
Standards for Privacy of Individually Identifiable Health Information; Modifications to the HIPAA Privacy Rule Required by the Genetic Information Nondiscrimination Act of 2008	0991-AB54
Standards for Privacy of Individually Identifiable Health Information; Modifications to the HIPAA Privacy Rule Under the Health Information Technology for Economic and Clinical Health Act	0991-AB57
Proposed Establishment of Certification Programs for Health Information Technology	0991-AB59

Office of the Secretary - Final Rule

Title	Regulation Identifier Number
Safe Harbor for Waiver of Beneficiary Co-Insurance and Deductible Amounts for a Medicare SELECT Policy	0991-AB16
Revisions to Procedures for the Departmental Appeals Board and Other Departmental Hearings	0991-AB42
HIPAA Administrative Simplification; Modifications to the HIPAA Enforcement Rule	0991-AB55
HIPAA Administrative Simplification; Notification in the Case of Breach	0991-AB56
Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology	0991-AB58

Office of the Secretary - Long-term Action

Title	Regulation Identifier Number
Shared Risk Exception to the Safe Harbor Provisions	0991-AA91
Rescission of the Regulation Entitled Ensuring That Department of Health and Human Services Funds Do Not Support Coercive of Discriminatory Policies or Practices in Violation of Federal Law	0991-AB49

Office of the Secretary - Completed Action

Title	Regulation Identifier Number
State Long-Term Care Partnership Program; Reporting Requirements for Insurers	0991-AB44
State Long-Term Care Partnership Program: State Reciprocity Standard	0991-AB47
Patient Safety and Quality Improvement Act of 2005; Civil Money Penalties Inflation Adjustment	0991-AB53

Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA) RIN: 0906-AA73

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Title: Add Vascularized Composite Allografts to the Definition of Organs Covered by the Rule Governing the Operation of the Organ Procurement and Transplantation Network (OPTN)

Abstract: The Department of Health and Human Services, Health Resources and Services Administration, Healthcare Systems Bureau, Division of Transplantation (DOT) plans to issue a notice of proposed rulemaking to include vascularized composite allografts (VCA) to the definition of 'organs' for purpose of coverage under NOTA and the OPTN final rule. NOTA authorizes the Secretary to include, by regulation, additional organs under the definition of organ. Currently, the OPTN final rule defines covered organs as "a human kidney, liver, heart, lung, or pancreas, or intestine (including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract). VCA transplantation comprises transplants of a variety of body parts (i.e. hand and face transplants) that are not currently regulated and which share common characteristics.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 121 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 301 of the National Organ Transplant Act (NOTA) of 1984, as amended; sec 371 to 376 of the Public Health Service Act; sec 1138 of the Social Security Act
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	05/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Agency Contact: Dr. Elizabeth Ortiz-Rios

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Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA) RIN: 0906-AA74

View Related Documents

Title: National Vaccine Injury Compensation Program: Separate Category for Hepatitis A, Influenza, Meningococcal, Human Papillomavirus Vaccines

Abstract: The Department of Health and Human Services proposes to change the Vaccine Injury Table (Table) to create separate categories for hepatitis A, trivalent influenza, meningococcal and human papillomavirus (HPV) vaccines. When a vaccine is recommended for routine administration to children by the Centers for Disease Control and Prevention (CDC), and after an excise tax is imposed on it by Congress, a vaccine is added to the Table under the new vaccines category (Category XIII). These four vaccines have been recommended for routine administration to children by the CDC and have had an excise tax imposed on them. Notices were published informing the public that these four vaccines have been added to the Table under Category XIII. The next step is that new vaccines are added as their own separate categories, with associated injuries/conditions, including the time periods in which the first symptoms or significant aggravation of such injuries/conditions must occur, if applicable, once the Secretary goes through the rulemaking process. In the past, such injuries/conditions have been added based on extensive scientific reviews of medical literature for adverse events following vaccination. Because reviews for these vaccines are not expected until 2011, at the earliest, we are proceeding with rulemaking to add these four vaccines as their own separate categories in order to make clear the four vaccines are covered by the National Vaccine Injury Compensation Program. Once results of the scientific reviews are published, additional rulemaking may be necessary, if certain conditions are viewed by the Department as appropriate for inclusion on the Table, including the relevant time periods of onset.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 42 CFR 100.3(c)(5) (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 2114(e)(2)of the Public Health Service Act, 42 USC 300ea-14(e)(2); sec 13632(a)(3) PL 103-66, 42 USC CFR 100.3(c)(5)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	06/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)

Health Resources and Services Administration (HRSA) RIN: 0906-AA77

View Related Documents

Title: Health Center Federal Tort Claims Act (FTCA) Medical Malpractice Program Regulations--Clarification of FTCA Coverage for Services Provided to Non-Health Center Patients

Abstract: The Bureau of Primary Health Care (BPHC) of the Health Resources and Services Administration (HRSA) proposes amending regulations at 42 CFR part 6 ("FTCA Coverage of Certain Grantees and Individuals") to include additional examples of Federal Tort Claims Act (FTCA)-covered activities. Recently, questions have arisen regarding the scope of FTCA regulations as they affect medical malpractice coverage for FTCA-deemed health centers and non-health center patients. Section 6.6(e) of the Health Center FTCA Program regulations provides examples of situations within the scope of section 6.6(d) (which authorizes FTCA medical malpractice coverage for non-health center patients). These examples include certain community-wide interventions and hospital-related activities where the health center's health care practitioners will be covered for services provided to non-health center patients.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 6 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 233
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	06/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA) RIN: 0906-AA57

View Related Documents

Title: National Practitioner Data Bank for Adverse Information on Physicians and Other Health Care Practitioners: Reporting Adverse and Negative Actions

Abstract: Public Law 100-93 amended section 1921 of the Social Security Act to require that each State has in effect a system of reporting disciplinary licensure actions taken against all licensed health care practitioners and entities. It also requires States to report any negative action or finding that a peer review organization, private accreditation entity, or a State has concluded against a health care practitioner or entity. Section 1921 directs the Secretary to provide for maximum appropriate coordination in the implementation of these reporting requirements with those of the Health Care Quality Improvement Act of 1986 (title IV of Pub. L. 99-660). Section 1921 requirements will be incorporated into the National Practitioner Data Bank.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 60 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1396r-2
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/21/2006	71 FR 14135
NPRM Comment Period End	05/22/2006	
Final Action	12/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA) RIN: 0906-AA44

View Related Documents

Title: Designation of Medically Underserved Populations and Health Professional Shortage Areas

Abstract: This rule would consolidate the processes for designating health professional shortage areas (HPSAs) and medically underserved areas and populations (MUA/MUPs) that apply in several Department programs, and would improve the criteria for designating MUA/Ps and Primary Care HPSAs. An NPRM was published on September 1, 1998, but due to the extensive comments received, another notice was published on June 3, 1999 announcing a decision to develop and publish a revised NPRM for public comment. The second NPRM was published on February 29, 2008, with the comment period extended twice (first on April 21, 2008, and again on June 2, 2008). Substantial comments were received that must be reviewed and considered. A Federal Register Notice published on July 23, 2008 announced an Agency decision to carefully review these comments, develop a modified proposal and publish another NPRM at a future date. Options are currently under development and consideration. A variety of Federal and State programs target resources to underserved populations using MUA/Ps and/or HPSAs. Statutory citations referenced above provide the legal foundation for the existing designations. While there is no statutory requirement to update MUA/P designations, there is such a requirement to update HPSAs. As a result, many MUA/Ps have not been updated, in some cases for over 20 years, and therefore may not reflect current conditions in many of these cases. However, to update these designations properly would likely involve revisions to the current methodologies to reflect changes in the prevailing values of the indicators and availability of data on other indicators of underservice. Alternatives are to continue to use the existing methodologies or develop another new approach for one or the other. Processing costs are anticipated to be minimal, in part because the infrastructure is already in place for the designation process, and it would simply involve implementing a different methodology.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 5; 42 CFR 51c (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 254b; 42 USC 254e
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Third NPRM	00/00/0000	
NPRM	09/01/1998	63 FR 46538
Second NPRM	02/29/2008	73 FR 11232
Second NPRM Comment Period Extended	04/21/2008	73 FR 21300
Second NPRM Initial Comment Period End	04/29/2008	
Second NPRM Extended Comment Period End	05/29/2008	
Second NPRM Second Comment Period Extended	06/02/2008	73 FR 31418
Second NPRM Second Extension of Comment Period End	06/30/2008	
NPRM Status	07/23/2008	73 FR 42743

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
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Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA)
RIN: 0906-AA76

View Related Documents

Title: Health Center Program Regulations--Consolidation With Migrant Health Center Program Regulations and Extension of Applicability to Health Care for the Homeless And Public Housing Primary Care Health

Abstract: HRSA proposes to amend its regulations at 42 CFR part 51c (the community health center regulations) to increase the consistency and improve the clarity of requirements across all health center types within the Health Center Program.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: 42 CFR 51c; 42 CFR 56 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 254b
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Next Action Undetermined		

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: No
Energy Affected: No
Related RINs: Merge with 0906-AA72
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Department of Health and Human Services (HHS)
Health Resources and Services Administration (HRSA)
RIN: 0906-AA78

View Related Documents

Title: Federal Tort Claims Act (FTCA) Coverage of Certain Grantees and Individuals: Covered Acts and Omissions-–Continuing Medical Education

Abstract: The Bureau of Primary Health Care (BPHC) of the Health Resources and Services Administration (HRSA)

withdraws its former proposal to issue a Notice of Proposed Rule Making to amend regulations at 42 CFR Part 6 (FTCA Coverage of Certain Grantees and Individuals) to include an additional example of Federal Tort Claims Act (FTCA) regarding Continuing Education Units.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 6 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 233
Legal Deadline: None

Timetable:

Action	Date	FR Cite
WIthdraw Rule	09/15/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AG06

View Related Documents

Title: Food Labeling: Safe Handling Statements, Labeling of Shell Eggs; Refrigeration of Shell Eggs Held for Retail Distribution

Abstract: Section 101.17(h) (21 CFR 101.17(h)) describes requirements for the labeling of the cartons of shell eggs that have not been treated to destroy Salmonella microorganisms. Section 115. 50 (21 CFR 115.50) describes requirements for refrigeration of shell eggs held for retail distribution. Section 16.5(a)(4) (21 CFR 16.5(a)(4)) provides that part 16 does not apply to a hearing on an order for relabeling, diversion, or destruction of shell eggs under section 361 of the Public Health Service Act (42 U.S.C. 264) and sections 101.17(h) and 115.50. FDA amended 21 CFR 101.17(h) on August 20, 2007 (72 FR 46375) to permit the safe handling statement to appear on the inside lid of egg cartons to provide the industry greater flexibility in the placement of the statement. FDA is undertaking a review of 21 CFR sections 101.17(h), 115.50, and 16.5(a)(4) under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations in sections 101.17(h), 115.50 and 16.5(a)(4) should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize any significant economic impact on a substantial number of small entities. FDA will consider, and is soliciting comments on, the following: (1) The continued need for the rule; (2) the nature of complaints or comments received concerning the rule from the public; (3) the complexity of the rule; (4) the extent to which the rule overlaps, duplicates, or conflicts with other Federal rules, and, to the extent feasible, with State and local governmental rules; and (5) the length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: PreRule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 101.17; 21 CFR 115.50; 21 CFR 16.5(a)(4) (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 15 USC 1453 to 1455; 21 USC 321; 21 USC 331; 21 USC 342 and 343; 21 USC 348; 21 USC 371; 42 USC 243; 42 USC 264; 42 USC 271
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Begin Review	12/00/2009	
End Review	12/00/2010	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG14

View Related Documents

Title: Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures

Abstract: FDA is undertaking a review of 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763) under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763) should be continued without change, or whether they should be amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize adverse impacts on a substantial number of small entities. FDA will consider, and is soliciting comments on, the following: (1) The continued need for the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763); (2) the nature of complaints or comments received from the public concerning the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763); (3) the complexity of the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763); (4) the extent to which the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763) overlap, duplicate, or conflict with other Federal rules, and to the extent feasible, with State and local governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by the regulations in 21 CFR part 203 and 21 CFR sections 205.3 and 205.50 (as amended in 64 FR 67762 and 67763).

Priority: Other Significant

Agenda Stage of Rulemaking: PreRule

Major: Undetermined

Unfunded Mandates: No

CFR Citation: 21 CFR 203; 21 CFR 205.3; 21 CFR 205.50 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 331; 21 USC 333; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 360; 21 USC 371; 21 USC 374; 21 USC 381

Legal Deadline:

Action	Source	Description	Date
Other	Statutory	Planned Section 610 Review	12/03/2009

Timetable:

Action	Date	FR Cite
Begin Review of Current Regulation	11/24/2008	
End Review of Current Regulation	12/00/2009	

Regulatory Flexibility Analysis Required: Business; Governmental Jurisdictions; Organizations

Government Levels Affected: Federal; Local; State

Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG25

View Related Documents

Title: Sterility Requirement for Aqueous-Based Drug Products for Oral Inhalation

Abstract: FDA is undertaking a review of 21 CFR 200.51, under section 610 of the Regulatory Flexibility Act. The purpose of this review is to determine whether this regulation on aqueous-based drug products for oral inhalation should be continued without change, or whether it should be amended or rescinded, consistent with the stated objectives of applicable statues, to minimize adverse impacts on a substantial number of small entities. FDA will consider, and is soliciting comments on the following: (1) The continued need for 21 CFR 200.51; (2) the nature of complaints or comments received concerning 21 CFR 200.51; (3) the complexity of 21 CFR 200.51; (4) the extent to which the regulation overlaps, duplicates, or conflicts with other Federal, State, or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed in the area affected by 21 CFR 200.51.

Priority: Other Significant
Agenda Stage of Rulemaking: PreRule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 21 CFR 200.51 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 358; 21 USC 360e; 21 USC 371; 21 USC 374; 21 USC 375
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	Planned section 610 review	05/26/2010

Timetable:

Action	Date	FR Cite
Begin Review	05/01/2009	
End Review	05/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)

Food and Drug Administration (FDA) RIN: 0910-AG34

View Related Documents

Title: Over-the-Counter Human Drugs; Labeling Requirements

Abstract: Part 201.66 (21 CFR section 201.66) established a standardized format for the labeling of OTC drug products that included: (1) Specific headings and subheadings presented in a standardized order, (2) standardized graphical features such as Helvetica type style and the use of “bullet points” to introduce key information, and (3) minimum standards for type size and spacing. FDA issued the final rule to improve labeling after considering comments submitted to the agency following the publication of the proposed regulation in 1997. In 1999, FDA published the final rule and stated that a standardized labeling format would significantly improve readability by familiarizing consumers with the types of information in OTC drug product labeling and the location of that information. In addition, a standardized appearance and standardized content, including various ”user-friendly” visual cues, would help consumers locate and read important health and safety information and allow quick and effective product comparisons, thereby helping consumers to select the most appropriate product. FDA is initiating a review under section 610 of the Regulatory Flexibility Act for the regulation in part 201.66. The purpose of this review is to determine whether the regulation in part 201.66 should be continued without change, or whether they should be further amended or rescinded, consistent with the stated objectives of applicable statutes, to minimize adverse impacts on a substantial number of small entities. FDA will consider, and is soliciting comments on the following: (1) The continued need for the regulation in part 201.66; (2) the nature of the complaints or comments received concerning the regulation in part 201.66; (3) the complexity of the regulations in part 201.66; (4) the extent to which the regulation in part 201.66 overlap, duplicate, or conflict with other Federal, State, or governmental rules; and (5) the degree to which technology, economic conditions, or other factors have changed for the products still subject to the labeling standard regulations in part 201. The section 610 review will be carried out along with a regulatory review under section 5 of Executive Order 12866, which calls for agencies to periodically review existing regulations to determine whether any should be modified or eliminated so as to make the agency’s regulatory program more effective in achieving its goals, less burdensome, or in greater alignment with the President's priorities and the principles set forth in the Executive order.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: PreRule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201.66 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 5 USC 610
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Begin Review of Current Regulation	08/03/2009	
End Review of Current Regulation	02/00/2010	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AC52

View Related Documents

Title: Electronic Submission of Data From Studies Evaluating Human Drugs and Biologics

Abstract: The Food and Drug Administration is proposing to amend the regulations governing the format in which clinical study data and bioequivalence data are required to be submitted for new drug applications (NDAs), biological license

applications (BLAs), and abbreviated new drug applications (ANDAs). The proposal would revise our regulations to require that data submitted for NDAs, BLAs, and ANDAs, and their supplements and amendments, be provided in an electronic format that FDA can process, review, and archive.

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Yes
Unfunded Mandates: Private Sector
CFR Citation: 21 CFR 314.50; 21 CFR 601.12; 21 CFR 314.94; 21 CFR 314.96 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 355; 21 USC 371; 42 USC 262
Legal Deadline: None

Regulatory Plan:

Statement of Need: Before a drug is approved for marketing, FDA must determine that the drug is safe and effective for its intended use. This determination is based in part on clinical study data and bioequivalence data that are submitted as part of the marketing application. Study data submitted to FDA in electronic format have generally been more efficient to process and review. FDA's proposed rule would require the submission of study data in a standardized electronic format. Electronic submission of study data would improve patient safety and enhance health care delivery by enabling FDA to process, review, and archive data more efficiently. Standardization would also enhance the ability to share study data and communicate results. Investigators and industry would benefit from the use of standards throughout the lifecycle of a study--in data collection, reporting, and analysis. The proposal would work in concert with ongoing agency and national initiatives to support increased use of electronic technology as a means to improve patient safety and enhance health care delivery.

Legal Basis: Our legal authority to amend our regulations governing the submission and format of clinical study data and bioequivalence data for human drugs and biologics derives from sections 505 and 701 of the Act (U.S.C. 355 and 371) and section 351 of the Public Health Service Act (42 U.S.C. 262).

Alternatives: FDA considered issuing a guidance document outlining the electronic submission and the standardization of study data, but not requiring electronic submission of the data in the standardized format. This alternative was rejected because the agency would not fully benefit from standardization until it became the industry standard, which could take up to 20 years. We also considered a number of different implementation scenarios, from shorter to longer time-periods. The 2-year time-period was selected because the agency believes it would provide ample time for applicants to comply without too long a delay in the effective date. A longer time-period would delay the benefit from the increased efficiencies, such as standardization of review tools across applications, and the incremental cost savings to industry would be small.

Costs and Benefits: Standardization of clinical data structure, terminology, and code sets will increase the efficiency of the agency review process. FDA estimates that the costs to industry resulting from the proposal would include some one-time costs and possibly some annual recurring costs. One-time costs would include, among other things, the cost of converting data to standard structures, terminology, and cost sets (i.e., purchase of software to convert data); the cost of submitting electronic data (i.e., purchase of file transfer programs); and the cost of installing and validating the software and training personnel. Additional annual recurring costs may result from software purchases and licensing agreements for use of proprietary terminologies. The proposal could result in many long-term benefits for industry, including improved patient safety through faster, more efficient, comprehensive, and accurate data review, as well as enhanced communication among sponsors and clinicians.

Risks: None.

Timetable:

Action	Date	FR Cite
NPRM	06/00/2010	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AC59

View Related Documents

Title: Reporting Information Regarding Falsification of Data

Abstract: The proposed rule would require sponsors to promptly report any information indicating that any person has or may have engaged in the falsification of data in the course of proposing, designing, performing, recording, supervising, or reviewing research, or in reporting research results.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: Undetermined

CFR Citation: 21 CFR 16.1; 21 CFR 58.11 and 58.12; 21 CFR 71.1; 21 CFR 101.69 and 101.70; 21 CFR 170.101; 21 CFR 171.1; 21 CFR 190.6; 21 CFR 312.56; 21 CFR 511.1; 21 CFR 571.1; 21 CFR 812.46 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 321; 21 USC 341 to 343; 21 USC 348 and 349; 21 USC 351 and 352; 21 USC 355; 21 USC 360b and 360c; 21 USC 360e; 21 USC 360i to 360k; 21 USC 361; 21 USC 371; 21 USC 379e; 42 USC 262

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/00/2010	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No

Federalism: No

Related RINs: Previously Reported as 0910-AC02

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF31

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Cough/Cold (Antihistamine) Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses antihistamine labeling claims for the common cold.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Reopening of Administrative Record	08/25/2000	65 FR 51780
NPRM (Amendment) (Common Cold)	09/00/2010	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF38

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Laxative Drug Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The final action will address laxative drug products. The first NPRM listed will address the professional labeling for sodium phosphate drug products. The second NPRM listed will address all other professional labeling requirements for laxative drug products.

Priority: Routine and Frequent Agenda Stage of Rulemaking: Proposed Rule
Major: No Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360 to 360a; 21 USC 371 to 371a
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM (Professional Labeling)	00/00/0000	
Final Action (Laxative Drug Products)	00/00/0000	
Final Action (Granular Psyllium)	03/29/2007	72 FR 14669
NPRM (Professional Labeling--Sodium Phosphate)	06/00/2010	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF43

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Sunscreen Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The first action addresses combination products containing sunscreen and insect repellent ingredients. The second action addresses active ingredients reviewed under Time and Extent Applications. The third action addresses other effectiveness issues for OTC sunscreen drug products. The fourth action is the final action that addresses sunscreen formulation, labeling, and testing requirements for both ultraviolet B and ultraviolet A radiation protection.

Priority: Other Significant Agenda Stage of Rulemaking: Proposed Rule
Major: No Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM (Sunscreen and Insect Repellent)	00/00/0000	
ANPRM (Sunscreen and Insect Repellent)	02/22/2007	72 FR 7941
ANPRM Comment Period End	05/23/2007	
NPRM (UVA/UVB)	08/27/2007	72 FR 49070
NPRM Comment Period End	12/26/2007	
NPRM (Effectiveness)	05/00/2010	
Final Action (UVA/UVB)	05/00/2010	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF44

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Vaginal Contraceptive Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The proposed rule addresses vaginal

contraceptive drug products.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 371; 21 USC 374; 21 USC 379e
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action (Warnings)	12/19/2007	72 FR 71769
NPRM (Vaginal Contraceptive Drug Products)	09/00/2010	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AF45

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Weight Control Products
Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The NPRM addresses the use of benzocaine for weight control. The first final action finalizes the 2005 proposed rule for weight control products containing phenylpropanolamine. The second final action will finalize the proposed rule for weight control products containing benzocaine.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action (Benzocaine)	00/00/0000	
NPRM (Phenylpropanolamine)	12/22/2005	70 FR 75988
Final Action (Phenylpropanolamine)	05/00/2010	
NPRM (Benzocaine)	05/00/2010	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes

Related RINs: Split From 0910-AA01

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF68

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Poison Treatment Drug Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses the ingredient ipecac syrup.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM (IPECAC)	06/00/2010	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF78

View Related Documents

Title: Import Tolerances for Unapproved New Animal Drugs

Abstract: The Food and Drug Administration (FDA) plans to publish a proposed rule related to the implementation of the import tolerances provision of the Animal Drug Availability Act of 1996 (ADAA). The ADAA authorizes FDA to establish tolerances for unapproved new animal drugs present in food of animal origin imported into the United States (import tolerances). It is unlawful to import animal-derived food that bears or contains residues of a new animal drug that is not approved in the United States, unless FDA has estalished an import tolerance for that new animal drug and the residue does not exceed that

tolerance.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 360b(a)(6); 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	08/00/2010	
NPRM Comment Period End	11/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AF82

View Related Documents

Title: Postmarket Safety Reporting for Combination Products

Abstract: The proposed rule would clarify the postmarket safety reporting requirements for combination products (combinations of a drug, device, and/or biological product). The proposed rule would provide a framework for the reporting of adverse events for combination products. The proposed rule would clarify that a combination product is subject primarily to the reporting requirements associated with the type of marketing application under which the product is approved or cleared. In addition, the proposed rule identifies unique reporting provisions that must be complied with if applicable. The regulation would ensure the consistency and appropriateness of postmarket safety reporting for combination products while avoiding the need for duplicative reporting requirements.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 4, subchapter B (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360c to 360f; 21 USC 360h to 360j; 21 USC 360l; 21 USC 360hh to 360ss; 21 USC 360aaa to 360bbb; 21 USC 371a; 21 USC 372 to 374; 21 USC 379e; 21 USC 381; 21 USC 394; 42 USC 216; 42 USC 262; 42 USC 263a; 42 USC 264; 42 USC 271
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	10/01/2009	74 FR 50744
NPRM Comment Period End	12/30/2009	
Final Action	08/00/2011	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: Business
Government Levels Affected: State
Federalism: Yes

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF87

View Related Documents

Title: Laser Products; Amendment to Performance Standard

Abstract: FDA is proposing to amend the performance standard for laser products to achieve closer harmonization between the current standard and the International Electrotechnical Commission (IEC) standard for laser products and medical laser products. The proposed amendment is intended to update FDA's performance standard to reflect advancements in technology. The proposal would adopt portions of an IEC standard to achieve greater harmonization and reflect current science. In addition, the proposal would include an alternative mechanism for providing certification and identification, address novelty laser products, and clarify the military exemption for laser products.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 1010; 21 CFR 1040 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 360hh-ss
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/00/2010	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
Energy Affected: Undetermined
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF88

View Related Documents

Title: Electronic Registration and Listing for Devices

Abstract: FDA is proposing to amend the medical device establishment registration and listing regulations at 21 CFR part 807 to reflect the electronic submission requirements in section 510(p) of the Federal Food, Drug, and Cosmetic Act (the Act). Section 510(p) was added to the Act by section 207 of the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), and later amended in September 2007 by section 224 of the Food and Drug Administration Amendments Act of 2007 (FDAAA). This proposed rule would require domestic and foreign device establishments to submit registration and listing data electronically via the Internet using FDA's Unified Registration and Listing System. This proposed rule would convert registration and listing to a paperless process. However, for those companies that do not have access to the Web, FDA would offer an avenue by which they can register, list, and update information with a paper submission. The proposed rule also would amend part 807 to reflect the timeframes for device establishment registration and listing established by sections 222 and 223 of FDAAA, and to reflect the requirement in section 510(i) of the Act, as amended by section 321 of the Public Health Security and Bioterrorism Preparedness and Response Act (BT Act), that foreign establishments provide FDA with additional pieces of information as part of their registration.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 807 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 110-85; PL 107-188, sec 321; PL 107-250, sec 207; 21 USC 360(a) through 360(j); 21 USC 360(p)
Legal Deadline: None

Regulatory Plan:

Statement of Need: FDA is proposing to amend the medical device establishment registration and listing requirements under 21 CFR part 807 to reflect the electronic submission requirements in section 510(p) of the Act, which was added by section 207 of MDUFMA and later amended by section 224 of FDAAA. FDA also is proposing to amend 21 CFR part 807 to reflect the requirements in section 321 of the BT Act for foreign establishments to furnish additional information as part of their registration. This proposed rule would improve FDA's device establishment registration and listing system and utilize the latest technology in the collection of this information.

Legal Basis: The statutory basis for our authority includes sections 510(a) through (j), 510(p), 701, 801, and 903 of the Act.

Alternatives: The alternatives to this rulemaking include not updating the registration and listing regulations. Because of the new FDAAA statutory requirements, and the advances in data collection and transmission technology, FDA believes this rulemaking is the preferable alternative.

Costs and Benefits: The Agency believes that there may be some one-time costs associated with the rulemaking, which involve resource costs of familiarizing users with the electronic system. Recurring costs related to submission of the information by domestic firms would probably remain the same or decrease because a paper submission and postage is not required. There might be some increase in the financial burden on foreign firms since they will have to supply additional registration information as required by section 321 of the BT Act.

Risks: None
Timetable:

Action	Date	FR Cite
NPRM	09/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
Energy Affected: Undetermined
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF89

View Related Documents

Title: Regulations on Fixed-Dose Combination and Co-Packaged Drug and/or Biological Products

Abstract: The proposed rule would amend FDA regulations on fixed-combination prescription and OTC drugs. The current regulations require, among other things, that the sponsor of a fixed-combination drug demonstrate that each of the components makes a contribution to the drug's claimed effects. The proposed rule would create a single set of regulations for prescription and OTC combination drugs and codify existing policy on what kinds of studies are needed to show that the combination drug requirements are met. The proposed rule also would apply these regulations to combinations of biological drug products and to drug-biological product combinations. In addition, the proposed rule would clarify application of FDA's requirements regarding fixed-dose combinations to certain natural source drugs and certain synthetic drugs. The regulation would also establish circumstances under which the agency might waive the combination requirements for a particular drug or biological product. The proposed rule will also address the issue of co-packaging.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 300.50; 21 CFR 330.10; 21 CFR 610.17 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 331; 21 USC 351 and 352; 21 USC 355; 21 USC 371; 42 USC 262; 42 USC 264
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	08/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF97

View Related Documents

Title: Proposed Revisions To Implement Portions of Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and Other Changes

Abstract: Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173) (MMA) amended provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that govern the approval of new drug applications (NDAs) described by section 505(b)(2) of the Act (505(b)(2) applications) and abbreviated new drug applications (ANDAs) described by section 505(j) of the Act. This proposed rule would implement portions of title XI of the MMA that pertain to: (1) Provision of notice to each patent owner and the NDA holder of certain patent certifications made by applicants submitting 505(b)(2) applications or ANDAs; (2) the availability of 30-month stays of approval on 505(b)(2) applications and ANDAs that are otherwise ready to be approved; (3) submission of amendments and supplements to 505(b)(2) applications and ANDAs; and (4) the types of bioavailability and bioequivalence data that can be used to support these applications. This proposed rule

also would amend certain regulations regarding 505(b)(2) applications and ANDAs to facilitate compliance with and efficient enforcement of the Act.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 21 CFR 314.3; 21 CFR 314.50; 21 CFR 314.52; 21 CFR 314.53; 21 CFR 314.60; 21 CFR 314.70; 21 CFR 314.90; 21 CFR 314.93; 21 CFR 314.94; 21 CFR 314.95; 21 CFR 314.96; 21 CFR 314.97; 21 CFR 314.99; 21 CFR 314.101; 21 CFR 314.105; 21 CFR 314.107; 21 CFR 314.108; 21 CFR 314.125; 21 CFR 314.127; 21 CFR 320.1; 21 CFR 320.23 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 108-173, title XI; 21 USC 355; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	06/00/2010	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Federalism: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AG02

View Related Documents

Title: Animal Food Labeling; Declaration of Certifiable Color Additives
Abstract: The Food and Drug Administration (FDA) is proposing to amend its regulations regarding the declaration of certified color additives on the labels of animal food including animal feeds and pet foods. FDA is proposing this amendment in response to the Nutrition Labeling and Education Act of 1990 (PL 101-535), which amended section 403 of the Federal Food, Drug, and Cosmetic Act (21 USC 343) by requiring, among other things, the listing on food labels of the common or usual names of all color additives required to be certified by FDA. An additional purpose of this amendment is to make these regulations consistent with the regulations regarding the declaration of certified color additives on the labels of human food. The proposed rule also suggests appropriate terminology for the declaration of certification-exempt color additives on the labels of animal food.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 501.22(k) (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 343(i)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/00/2009	
NPRM Comment Period End	01/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: Undetermined

International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG07

View Related Documents

Title: Conditional Approval of New Animal Drugs for Minor Use and Minor Species

Abstract: This proposed rule implements section 571 of the Food, Drug, and Cosmetic Act. The Minor Use and Minor Species Animal Health Act of 2004 (MUMS act) added three sections to the Federal Food, Drug, and Cosmetic Act (the Act) (571, 572, and 573), and it established new regulatory procedures intended to make more medications legally available to veterinarians and animal owners for the treatment of minor animal species, as well as uncommon diseases in major animal species. Section 571 of the Act provides for animal drug conditional approval after all safety and manufacturing components of a new animal drug approval have met the standards of section 512 of the Act. For the effectiveness component of a new animal drug review, a reasonable expectation of effectiveness must be established prior to conditional approval under section 571 of the Act. Sponsors then have up to 5 years to complete the demonstration of effectiveness by the standards of section 512 of the Act and achieve a complete new animal drug approval.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 516 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 360ccc; 21 USC 371
Legal Deadline:

Action	Source	Description	Date
NPRM	Statutory		02/00/2011

Timetable:

Action	Date	FR Cite
NPRM	10/00/2010	
NPRM Comment Period End	01/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG08

View Related Documents

Title: Animal Feed Ingredient Standards and Definitions

Abstract: The President signed into law the Food and Drug Administration Amendments Act of 2007 (FDAAA) on September 27, 2007. The FDAAA includes several provisions pertaining to food safety, including the safety of pet food. FDAAA section 1002(a)(1) directs FDA to issue new final regulations within 2 years to establish pet food ingredient standards and definitions. This same provision of the law also directs that, in developing these new regulations, FDA consult with the Association of American Feed Control Officials and other relevant stakeholder groups, including veterinary medical associations, animal health organizations, and pet food manufacturers.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 341; 21 USC 371; PL 110-85, sec 1002(a)(1)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	FDA must issue proposed and final regulations by the statutory deadline.	09/27/2009

Timetable:

Action	Date	FR Cite
NPRM	10/00/2010	
NPRM Comment Period End	01/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AG09

View Related Documents

Title: Pet Food Labeling Requirements

Abstract: The President signed into law the Food and Drug Administration Amendments Act of 2007 (FDAAA) on September 27, 2007 (Pub. L. 110-85). Title X of the FDAAA includes several provisions pertaining to food safety, including the safety of pet food. Section 1002(a) of the new law directs that, within 2 years, FDA is to issue new regulations to establish updated standards for the labeling of pet food that include nutritional and ingredient information. This same provision of the law also directs that, in developing these new regulations, FDA obtain input from its stakeholders, including the Association of American Feed Control Officials, veterinary medical associations, animal health organizations, and pet food manufacturers.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 343; 21 USC 371; PL 110-85, sec 1002(a)(3)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	FDA must issue proposed and final regulations by the statutory deadline.	09/27/2009

Timetable:

Action	Date	FR Cite
NPRM	10/00/2010	
NPRM Comment Period End	01/00/2011	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: No

Small Entities Affected: Business

Federalism: No

Energy Affected: No

International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG10

View Related Documents

Title: Process Controls for Animal Feed Ingredients and Mixed Animal Feed

Abstract: The Food and Drug Administration (FDA) is proposing regulations for process controls for animal feed ingredients and mixed animal feed to provide greater assurance that marketed animal feed ingredients and mixed feeds intended for all animals, including pets, are safe. This action is being taken as part of the FDA's Animal Feed Safety System initiative. The proposed process controls will apply to animal feed ingredients and mixed animal feed including pet food. This action is also being taken to carry out the requirements of the Food and Drug Administration Amendments Act of 2007. Section 1002(a) directs FDA to establish by regulation processing standards for pet food. This same provision of the law also directs that, in developing these new regulations, FDA obtain input from its stakeholders, including the Association of American Feed Control Officials, veterinary medical associations, animal health organizations, and pet food manufacturers.

Priority: Other Significant

Agenda Stage of Rulemaking: Proposed Rule

Major: No

Unfunded Mandates: No

CFR Citation: 21 CFR 228 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 342; 21 USC 371; PL 110-85, sec 1002(a)(2)

Legal Deadline:

Action	Source	Description	Date
Other	Statutory	FDA must issue proposed and final regulations by the statutory deadline.	09/27/2009

Timetable:

Action	Date	FR Cite
NPRM	10/00/2010	
NPRM Comment Period End	01/00/2011	

Regulatory Flexibility Analysis Required: Business

Government Levels Affected: No

Federalism: No

International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG12

View Related Documents

Title: Pediatric Dosing for Cough, Cold, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a monograph is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action will propose changes to the final monograph to address safety and efficacy issues associated with pediatric cough and cold products.

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Yes
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	06/00/2010	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
Energy Affected: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.
Related RINs: Related to 0910-AF31; Related to 0910-AF32; Related to 0910-AF33; Related to 0910-AF34
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG15

View Related Documents

Title: Revision of the Requirements for Constituent Materials

Abstract: Constituent materials include ingredients, preservatives, diluents, adjuvants, extraneous protein, and antibiotics that are contained in a biological product. This action will allow flexibility for manufacturing biological products, including innovative lifesaving products, that do not currently comply with the requirements for constituent materials but have been demonstrated to

be safe, pure, and potent products. FDA is amending the regulation for constituent materials to allow the Director of the Center for Biologics Evaluation and Research (CBER) and the Director of the Center for Drugs Evaluation and Research (CDER) to approve an exception or alternative to the requirements under section 610.15, when the exception or alternative is sufficient to ensure acceptable levels of safety, purity, and potency of the biological product. This rule provides manufacturers of innovative biological products and manufacturers of currently approved products with flexibility, as appropriate, to take advantage of advances in science and technology as they become available, provided that the manufacturer demonstrates that the product will meet (or continue to meet) generally accepted standards of purity and quality.

Priority: Info./Admin./Other
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 610.15 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 360; 21 USC 360c; 21 USC 360d; 21 USC 360h; 21 USC 360i; 21 USC 371; 21 USC 372; 21 USC 374; 21 USC 381; 42 USC 216; 42 USC 262; 42 USC 263; 42 USC 263a; 42 USC 264
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Direct Final Rule	03/00/2010	
NPRM	03/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AG16

View Related Documents

Title: Amendments to Sterility Testing Requirements for Biological Products
Abstract: The Food and Drug Administration (FDA) is issuing a proposed rule to amend the sterility testing requirements for biological products. This proposed rule is intended to provide manufacturers of biological products greater flexibility and to encourage use of the most appropriate and state-of-the-art methodologies to ensure the safety of biological products.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 610.12 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 360; 21 USC 360c; 21 USC 360d; 21 USC 360h; 21 USC 360i; 21 USC 371; 21 USC 372; 21 USC 374; 21 USC 381; 42 USC 216; 42 USC 262; 42 USC 263; 42 USC 263a; 42 USC 264
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG17

View Related Documents

Title: New Animal Drugs: Updating Tolerances for Residues in New Animal Drugs in Food

Abstract: FDA is proposing to revise 21 CFR 556 to reformat the listings of tolerances for residues of approved new animal drugs in food. This revision will standardize, simplify, and clarify these listings, and improve the readability of the regulations. Currently, part 556 employs a patchwork of various styles for listing tolerances that have evolved over the past 40 years as each additional animal drug has been approved. The listings in part 556 are not uniform in format, and FDA does not always provide relevant information in a clear and straightforward manner. For example, FDA provides the acceptable daily intake (ADI) and safe concentrations for some, but not all drugs; FDA lists some tolerances as being for "negligible" residues, and FDA presents some listings in a text paragraph format while others are presented in outline form. Moreover, sometimes FDA specifies “no residue,” “zero tolerance,” or tolerance “not required” but does not define or make distinction between these important terms.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 556 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 360b
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	06/00/2010	
NPRM Comment Period End	09/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG18

View Related Documents

Title: Electronic Distribution of Content of Labeling for Human Prescription Drug and Biological Products

Abstract: This rule would require electronic package inserts for human drug and biological prescription products, in lieu of paper, which is currently used. This would ensure that the information accompanying the product is the most up-to-date information regarding important safety and efficacy issues about these products.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201.100; 21 CFR 201.306; 21 CFR 201.310 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 360b; 21 USC 360gg - 360ss; 21 USC 371; 21 USC 374; 21 USC 379e; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 264
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/00/2010	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AG20

View Related Documents

Title: Amendment to the Current Good Manufacturing Practice Regulations for Finished Pharmaceuticals
Abstract: The Food and Drug Administration (FDA) periodically reassesses and revises the cGMP regulations to accommodate advances in technology and other scientific knowledge that further safeguard the drug manufacturing process and the public health. In August 2002, FDA announced the Pharmaceutical cGMPs for the 21st Century Initiative. As part of the Initiative, FDA created a cGMP Harmonization Analysis Working Group to analyze related cGMP requirements in the United States and internationally. The cGMP working group compared 21 CFR parts 210 and 211 with the cGMPs of the European Union, as well as other FDA regulations (such as the Quality Systems Regulation in 21 CFR part 820) to identify differences and consider the value of supplementing or changing the current regulations. Based on the cGMP Working Group's analysis, FDA decided to take an incremental approach to modifying 21 CFR parts 210 and 211. In September of 2008, FDA published a final rule revising the cGMP regulations primarily in the areas of aseptic processing, use of asbestos filters, and verification of operations by a second individual; this final rule represented the culmination of the first increment of modifications to the cGMP regulations. The proposed rule identified on this Unified Agenda would begin the second increment of modifications to the cGMP regulations.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: 21 CFR 210; 21 CFR 211 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 351; 21 USC 352; 21 USC 355; 21 USC 360b; 21 USC 371; 21 USC 374; 42 USC 216; 42 USC 262; 42 USC 263a; 42 USC 264
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/00/2010	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Small Entities Affected: Business
Federalism: No
Energy Affected: Undetermined
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG24

View Related Documents

Title: Minor Amendment to New Animal Drug Applications

Abstract: This direct final rule is being issued to amend 21 CFR 514.1 so as to provide that new animal drug applications shall be submitted in the form described in the section, as appropriate for the particular submission. Currently, the regulation requires that all new animal drug applications contain the same informational sections and does not clearly provide the appropriate flexibility needed to address the development of novel new animal drug products. This amendment will allow the agency to review appropriate safety and effectiveness data to support new animal drug products. In addition, the amendment is similar to the language contained in the human drug application regulations at 21 CFR 314.50 (Applications and supplements to applications are required to be submitted in the form and contain the information, as appropriate for the particular submission, required under this section.)

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 514.1 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 360b(b)(1); 21 USC 371(a)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Direct Final Rule	10/23/2009	74 FR 54749
NPRM	10/23/2009	74 FR 54771
NPRM Comment Period End	01/06/2010	
Confirmation of Effective Date	02/00/2010	
Direct Final Rule Effective	03/08/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG26

View Related Documents

Title: Amendments to Regulations on Citizen Petitions, Petitions for Stay of Action, and Submission of Documents to Dockets; Implementation of Section 505(q) of the Federal Food, Drug, and Cosmetic Act

Abstract: The Food and Drug Administration (FDA) is proposing to amend certain regulations relating to citizen petitions, petitions for stay of action, and the submission of documents to the agency. We are making these changes to implement provisions in section 914 of title IX of the Food and Drug Administration Amendments Act, which added section 505(q) to the Federal Food, Drug, and Cosmetic Act (the act). In particular, the proposed rule would establish new regulations to implement section 505(q) of the act, which concerns certain citizen petitions and petitions for stay of action that involve a request for FDA to take any form of action relating to a pending application submitted under section 505(b)(2) or (j) of the act. Among other things, section 505(q)(1)(F) of the Act governs the time frame for final Agency action on a petition subject to section 505(q). In addition, under section 505(q)(1)(H) of the act, FDA may not consider a petition for review unless the petition is in writing and signed and contains a certification that is specified in that section.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No

CFR Citation: 21 CFR 10.20; 21 CFR 10.30 and 10.31; 21 CFR 10.35; ... (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 5 USC 551 to 558; 5 USC 701 to 706; 15 USC 1451 to 1461; 21 USC 141 to 149; 21 USC 321 to 397; 21 USC 467f; 21 USC 679; 21 USC 821; 21 USC 1034; 28 USC 2112; 42 USC 201; 42 USC 262; 42 USC 263b; 42 USC 364

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/00/2010	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: No

Federalism: No

Energy Affected: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG27

View Related Documents

Title: Direct-to-Consumer Prescription Drug Advertisements: Presentation of the Major Statement in Television and Radio Advertisements in a Clear, Conspicuous, and Neutral Manner

Abstract: The Food and Drug Administration (FDA) is proposing to amend its regulations concerning direct-to-consumer (DTC) advertisements of prescription drugs. Advertisements broadcast through media must disclose the product's major risks in what is sometimes called the "major statement." The proposed rule would implement provisions of the Food and Drug Administration Amendments Act of 2007 (FDAAA) by requiring that the major statement in DTC television and radio advertisements relating to the side effects and contraindications of an advertised prescription drug be presented in a clear, conspicuous, and neutral manner. FDA is also proposing, as directed by FDAAA, standards that would be considered in determining whether the major statement in these advertisements is presented in the manner required by FDAAA.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 21 CFR 202.1 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 331; 21 USC 352; 21 USC 355; 21 USC 360b; 21 USC 371; ...
Legal Deadline: Issuance of rule required by section 901(d)(3)(B) of the Food and Drug Administration Amendments Act of 2007.

Action	Source	Description	Date
NPRM	Statutory		03/27/2010

Timetable:

Action	Date	FR Cite
NPRM	03/00/2010	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AG28

View Related Documents

Title: Animal Drugs, Feeds, and Related Products; Regulation of Carcinogenic Compounds in Food-Producing Animals
Abstract: The Food and Drug Administration (FDA) plans to publish a proposed rule to amend the regulations regarding carcinogenic compounds used in food-producing animals. No food additive or drug can be deemed safe for use in a food if it is found to induce cancer in man or animals. An exception can be made if it can found that (1) an animal feed additive or veterinary drug will not adversely affect the animal and (2) no residue of the animal feed additive or veterinary drug will be found in any edible portion of that animal. The approach permits the determination of the quantity of carcinogenic residues that may be consumed daily with no significant increase in the risk of cancer to people. This quantity is termed the So. The So is currently defined in regulation as the concentration of the carcinogenic compound that corresponds to a maximum lifetime risk to the test animals of 1 in 1 million. The total residues of carcinogenic concern in edible tissues derived from the So are termed the Sm. FDA believes that a careful reading of the December 31, 1987 (52 FR 49586) final rule, suggests that an emphasis on no significant increased risk, rather than on the specific 1 in 1 million approach, reflects the original intent of the regulation. Specifically, FDA is proposing a revision to the definition of “So” for clarification purposes so that the term primarily means the concentration of residue of carcinogenic concern in the total human diet that represents no significant increase in the risk of cancer to people. FDA is also proposing a redefinition of Sm to conform to the definition of So as described above. Specifically, Sm would mean the concentration of residue of carcinogenic concern in a specific edible tissue corresponding to no significant increase in the risk of cancer to people. Other clarifying and conforming changes are also being proposed. FDA is publishing this proposed rule as a companion document to a document being published elsewhere in accordance with FDA’s direct final rule procedures.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 500.82 and 500.84 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 360b(d)(1)(I)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	08/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AG29

View Related Documents

Title: Requirement for Submission of Information on Pediatric Subpopulations That Suffer From a Disease or Condition That a Device Is Intended to Treat, Diagnose, or Cure

Abstract: The regulation is implementing section 515A(a) by requiring applicants who submit premarket approval applications (PMAs), product development protocols (PDPs), and applications for humanitarian device exemptions (HDEs) to include readily available information regarding the potential pediatric use of their medical device. These applications must include: A description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose or cure; and the number of affected pediatric patients. The information submitted will allow FDA to track the number of approved devices for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure; the number of approved devices labeled for use in pediatric patients; the number of approved pediatric devices that were exempted from a review fee pursuant to section 738(a)(2)(B)(v) of the act; and the review time for each such device.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No

CFR Citation: 21 CFR 814.1(a); 21 CFR 814.2; 21 CFR 814.20(b)(3)(i); 21 CFR 814.37(b); 21 CFR 814.39(h); 21 CFR 814.44(e)(1); 21 CFR 814.100(a)(c); 21 CFR 814.104(b); 21 CFR 814.116(c); ... (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: Title III of the Food Drug Administration Amendments Act of 2007, which includes new section 515A, is also known as the pediatric Medical Device Safety and Improvement Act of 2007.

Legal Deadline: None

Timetable:

Action	Date	FR Cite
Direct Final Rule	09/00/2010	
NPRM	09/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: Undetermined
Energy Affected: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG32

View Related Documents

Title: Informed Consent Elements

Abstract: The proposed rule is to implement section 801(b)(3)(A) of the Food and Drug Administration Amendments Act of 2007. The provision requires the Food and Drug Administration to update its informed consent regulations to require inclusion in the informed consent documents and process a statement that clinical trial information for such clinical investigation has been or will be submitted for inclusion in the registry data bank pursuant to subsection (j) of section 402 of the Public Health Service Act (PHSA). The regulation will require the insertion of a specific statement in all informed consent documents that, if applicable, the clinical trial information for such clinical investigation has been or will be submitted for inclusion in the registry data bank pursuant to subsection (j) of section 402 of the PHSA.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 50.25 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 355(i)(4); 21 USC 360j(g)(3)(D); 21 USC 371(a); secs 505(i), 520(g), and 701(a), FD&C Act
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/00/2009	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Federal
Small Entities Affected: Business; Organizations
Federalism: No
Energy Affected: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG35

View Related Documents

Title: Produce Safety Regulation

Abstract: The Food and Drug Administration is proposing to promulgate regulations setting enforceable standards for fresh produce safety at the farm and packing house. The purpose of the proposed rule is to reduce the risk of illness associated with contaminated fresh produce. The proposed rule will be based on prevention-oriented public health principles and incorporate what we have learned in the past decade since the agency issued general good agricultural practice guidelines entitled “Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables” (GAPs Guide). The proposed rule also will reflect comments received on the agency's 1998 update of its GAPs guide and its July 2009 draft commodity specific guidances for tomatoes, leafy greens, and melons. Although the proposed rule will be based on recommendations that are included in the

GAPs guide, it does not make the entire guidance mandatory. FDA's proposed rule would, however, set out clear standards for implementation of modern preventive controls. The proposed rule also would emphasize the importance of environmental assessments to identify hazards and possible pathways of contamination and provide examples of risk reduction practices recognizing that operators must tailor their preventive controls to particular hazards and conditions affecting their operations. The requirements of the proposed rule would be scale appropriate and commensurate with the relative risks and complexity of individual operation. FDA intends to issue guidance after the proposed rule is finalized to assist industry in complying with the requirements of the new regulation.

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Yes
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 342; 21 USC 371; 42 USC 264
Legal Deadline: None

Regulatory Plan:

Statement of Need: FDA has determined that enforceable standards (as opposed to voluntary recommendations) for the production and packing of fresh produce are necessary to ensure best practices are commonly adopted.

Legal Basis: FDA's legal basis derives in part from sections 402(a)(4) and 701(a) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 342(a)(4) and 371(a)). The agency has promulgated regulations that respond to a number of the provisions of the 1986 amendments. This final rule would address additional provisions of these amendments.

Alternatives: An alternative to this rulemaking would be to update FDA's 1998 GAPs Guide. However, even though the 1998 guidance has been well received and widely adopted, outbreaks associated with fresh produce continue. Outbreak investigations also continue to observe conditions and practices that are not consistent with the voluntary recommendations. FDA believes a regulation containing clear, enforceable standards would be more effective in ensuring best practices are widely adopted.

Costs and Benefits: FDA estimates that the costs to more than 300,000 domestic and foreign producers and packers of fresh produce from the proposal would include one-time costs (e.g., new tools and equipment) and recurring costs (e.g., monitoring, training, recordkeeping). FDA anticipates that the benefits would be a reduction in foodborne illness and deaths associated with fresh produce. Monetized estimates of costs and benefits are not available at this time.

Risks: This regulation would directly and materially advance the Federal Government's substantial interest in reducing the risks for illness and death associated with foodborne infections resulting from the consumption of contaminated fresh produce. Less restrictive and less comprehensive approaches have not been effective in reducing the problems addressed by this regulation. FDA anticipates that the regulation would lead to a significant decrease in foodborne illness associated with fresh produce in the U.S.

Timetable:

Action	Date	FR Cite
NPRM	10/00/2010	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: No
Federalism: Undetermined
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AG36

View Related Documents

Title: Modernization of the Current Food Good Manufacturing Practices Regulation

Abstract: The Food and Drug Administration (FDA) is proposing to amend its current good manufacturing practices (CGMP) regulations (21 CFR part 110) for manufacturing, packing, or holding human food. This proposed rule would require food facilities to address issues such as environmental pathogens, food allergens, mandatory employee training, and sanitation of food contact surfaces. The proposed rule also would require food facilities to develop and implement preventive control systems. FDA is taking this action to better address changes that have occurred in the food industry and thereby protect public health.

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Yes
Unfunded Mandates: No
CFR Citation: 21 CFR 110 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 342; 21 USC 371; 42 USC 264
Legal Deadline: None

Regulatory Plan:

Statement of Need: FDA last updated its food CGMP regulations for manufacturing, packing or holding of human food in 1986. Modernizing these food CGMP regulations to more explicitly address issues such as environmental pathogens, food allergens, mandatory employee training, and sanitation of food contact surfaces, as well as risk-based preventive controls, would be a critical step in raising the standards for food production and distribution. By amending 21 CFR 110 to modernize good manufacturing practices, the agency could focus the attention of food processors on measures that have been proven to significantly reduce the risk of food-borne illness. An amended regulation also would allow the agency to better focus its regulatory efforts on ensuring industry compliance with controls that have a significant food safety impact.

Legal Basis: FDA's legal authority to amend its CGMP regulations derives in part from sections 402(a)(3), (a)(4) and 701(a) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 342(a)(3), (a)(4), and 371(a)). Under section 402(a)(3) of the Act, a food is adulterated if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food. Under section 402(a)(4), a food is adulterated if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth or may have been rendered injurious to health. Under section 701(a) of the Act, FDA is authorized to issue regulations for the efficient enforcement of the Act. FDA's legal basis also derives from section 361 of the Public Health Service Act (PHS Act) (42 U.S.C. 264), which gives FDA authority to promulgate regulations to control the spread of communicable disease.

Alternatives: An alternative to this rulemaking is not to update the CGMP regulations, and instead to issue guidance on best practices regarding environmental pathogens, food allergens, mandatory employee training, sanitation of food contact surfaces, and risk-based preventive controls. However, guidance is voluntary and unenforceable. FDA believes a regulation containing clear, enforceable standards would be more effective in ensuring protection of public health.

Costs and Benefits: FDA estimates that the costs from the proposal to domestic and foreign producers and packers of processed foods would include new one-time costs (e.g., adoption of written food safety plans, setting up training programs, implementing allergen controls, and purchasing new tools and equipment) and recurring costs (e.g., auditing and monitoring suppliers of sensitive raw materials and ingredients, training employees, and completing and maintaining records used throughout the facility). FDA anticipates that the benefits would be a reduced risk of foodborne illness and deaths from processed foods and from a reduction in the number of safety related recalls.

Risks: This regulation will directly and materially advance the federal government's substantial interest in reducing the risks for illness and death associated with foodborne infections. Less restrictive and less comprehensive approaches have not been effective in reducing the problems addressed by this regulation. The regulation will lead to a significant decrease in foodborne illness in the U.S.

Timetable:

Action	Date	FR Cite
NPRM	10/00/2010	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: No
Federalism: Undetermined
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AA49

View Related Documents

Title: Foreign and Domestic Establishment Registration and Listing Requirements for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs

Abstract: The rule will reorganize, consolidate, clarify, and modify current regulations at 21 CFR part 207 concerning who must register establishments and list human drugs, certain biological drugs, and animal drugs. These regulations contain information on when, how, and where to register drug establishments and list drugs, and what information must be submitted for initial registration and listing and for changes to registration and listing. The rule will require that this information be submitted electronically. The rule will also make certain changes to the National Drug Code (NDC) system and would require that the appropriate human-readable NDC number appear on certain drug labels.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No

CFR Citation: 21 CFR 20; 21 CFR 201; 21 CFR 207; 21 CFR 314; 21 CFR 330; 21 CFR 514 and 515; 21 CFR 601; 21 CFR 607; 21 CFR 610; 21 CFR 1271 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 and 352; 21 USC 355; 21 USC 360; 21 USC 360b; 21 USC 371; 21 USC 374; 42 USC 262; 42 USC 264; 42 USC 271

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	08/29/2006	71 FR 51276
NPRM Comment Period End	02/26/2007	
Final Action	09/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No

International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AA97

View Related Documents

Title: Postmarketing Safety Reporting Requirements for Human Drug and Biological Products

Abstract: The final rule would amend the postmarketing expedited and periodic safety reporting regulations for human drugs and biological products to revise certain definitions and reporting formats as recommended by the International Conference on Harmonisation and to define new terms; to add to or revise current reporting requirements; to revise certain reporting time frames; and to propose other revisions to these regulations to enhance the quality of safety reports received by FDA. These revisions were proposed as part of a single rulemaking (68 FR 12406) to clarify and revise both premarketing and postmarketing

safety reporting requirements for human drug and biological products. FDA plans to finalize the premarket and postmarket safety reporting requirements in separate final rules.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: Yes
Unfunded Mandates: No
CFR Citation: 21 CFR 310; 21 CFR 314; 21 CFR 600 and 601; 21 CFR 606 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 216; 42 USC 241; 42 USC 242a; 42 USC 262 and 263; 42 USC 263a to 263n; 42 USC 264; 42 USC 300aa; 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360b to 360j; 21 USC 361a; 21 USC 371; 21 USC 374; 21 USC 375; 21 USC 379e; 21 USC 381
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/14/2003	68 FR 12406
NPRM Comment Period Extended	06/18/2003	
NPRM Comment Period End	07/14/2003	
NPRM Comment Period Extension End	10/14/2003	
Final Action	09/00/2010	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: No
Federalism: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AC25

View Related Documents

Title: Exception From General Requirements for Informed Consent; Request for Comments and Information
Abstract: This final rule will affirm the interim final rule's exception from the general requirement for informed consent in certain circumstances involving the use of investigational in vitro diagnostic devices to identify chemical, biological, radiological, or nuclear agents in a potential terrorist event or other public health emergency. The agency is issuing this rule because it is concerned that, during a potential terrorism event or other public health emergency, delaying testing of specimens to obtain informed consent may threaten the life of the subjects or others who have been exposed to or who may be at risk of exposure to a chemical, biological, radiological, or nuclear agent.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 50.23 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 343; 21 USC 346 to 346a; 21 USC 348; 21 USC 350a to 350b; 21 USC 352; 21 USC 353; 21 USC 355; 21 USC 360; 21 USC 360c to 360f; 21 USC 360h to 360j; 21 USC 371; 21 USC 379e; 21 USC 381; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 263b to 263n
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Interim Final Rule	06/07/2006	71 FR 32827
Interim Final Rule Comment Period End	08/07/2006	
Final Action	09/00/2010	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Government Levels Affected: State
Federalism: Yes

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AC30

View Related Documents

Title: Medical Devices; Anesthesiology Devices; Reclassification of Pressure Regulators for Use With Medical Oxygen and Separate Classification of Oxygen Conserving Devices

Abstract: The Food and Drug Administration (FDA) is reclassifying pressure regulators for use with medical oxygen from class I to class II, establishing a separate classification for oxygen conserving devices, and establishing a special control for these devices to address problems of fire and explosion associated with use of these devices. The special control will be a guidance document that includes standardized testing, performance, and labeling guidance for industry. Devices that meet the standard identified in the special controls guidance document will be exempt from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (the Act). The requirements of the final rule will be phased-in to minimize the cost of complying with the special control.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 868.2700; 21 CFR 868.2750; 21 CFR 868.5905; 21 CFR 868.5910 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 351; 21 USC 360; 21 USC 360c; 21 USC 360e; 21 USC 360j; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	02/27/2007	72 FR 8643
NPRM Comment Period End	05/29/2007	
Final Action	09/00/2010	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined
Energy Affected: Undetermined

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AC53

View Related Documents

Title: Medical Gas Containers and Closures; Current Good Manufacturing Practice Requirements

Abstract: The Food and Drug Administration is amending its current good manufacturing practice regulations and other regulations to clarify and strengthen requirements for the label, color, dedication, and design of medical gas containers and closures. Despite existing regulatory requirements and industry standards for medical gases, there have been repeated incidents in which cryogenic containers of harmful industrial gases have been connected to medical oxygen supply systems in hospitals and nursing homes, and subsequently administered to patients. These incidents have resulted in death and serious injury. There have also been several incidents involving high-pressure medical gas cylinders that have resulted in death and injuries to patients. These amendments, together with existing regulations, are intended to ensure that the types of incidents that have occurred in the past, as well as other types of foreseeable and potentially deadly medical gas accidents, do not occur in the future.

Priority: Other Significant Agenda Stage of Rulemaking: Final Rule
Major: No Unfunded Mandates: No
CFR Citation: 21 CFR 201.161(a); 21 CFR 211.94; 21 CFR 211.125 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 351 to 21 USC 353
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/10/2006	71 FR 18039
NPRM Comment Period End	07/10/2006	
Final Action	06/00/2010	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AC55

View Related Documents

Title: Positron Emission Tomography Drugs; Current Good Manufacturing Practices

Abstract: Section 121 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) directs FDA to establish requirements for current good manufacturing practices (CGMPs) for positron emission tomography (PET) drugs, a type of radiopharmaceutical. The final rule would adopt CGMPs that reflect the unique characteristics of PET drugs.

Priority: Other Significant Agenda Stage of Rulemaking: Final Rule
Major: No Unfunded Mandates: No
CFR Citation: 21 CFR 212 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 105-115, sec 121
Legal Deadline:

Action	Source	Description	Date

Other	Statutory		11/21/1999

Timetable:

Action	Date	FR Cite
NPRM	09/20/2005	70 FR 55038
NPRM Comment Period End	12/19/2005	
Final Action	12/00/2009	

Regulatory Flexibility Analysis Required: Governmental Jurisdictions

Government Levels Affected: Federal; State

Federalism: No

Energy Affected: No

RIN Information URL: www.fda.gov/cder/regulatory/pet

Related RINs: Previously Reported as 0910-AB63

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF11

View Related Documents

Title: Content and Format of Labeling for Human Prescription Drugs and Biologics; Requirements for Pregnancy and Lactation Labeling

Abstract: To amend the regulations governing the format and content of labeling for human prescription drugs and biological products (21 CFR parts 201.56, 201.57, and 201.80). Under FDA's current regulations, labeling concerning the use of prescription drugs in pregnancy uses letter categories (A, B, C, D, X) to characterize the risk to the fetus of using the drug in pregnancy. Dissatisfaction with the category system has been expressed by health care providers, medical organizations, experts in the study of birth defects, women's health researchers, and women of childbearing age. Stakeholders consulted through a public hearing, several focus groups, and several advisory committees have recommended that FDA replace the category system with a concise narrative summarizing a product's risks to pregnant women and to women of childbearing age. The revised format and the information provided in the labeling would make it easier for health care providers to understand the risks and benefits of drug use during pregnancy and lactation.

Priority: Other Significant

Agenda Stage of Rulemaking: Final Rule

Major: No

Unfunded Mandates: No

CFR Citation: 21 CFR 201.56 and 201.57; 21 CFR 201.80 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 360b; 21 USC 360gg to 360ss; 21 USC 371; 21 USC 374; 21 USC 379e; 42 USC 216; 42 USC 241; 42 USC 262; 42 USC 264

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	05/29/2008	73 FR 30831
NPRM Comment Period End	08/27/2008	
Final Action	04/00/2010	

Regulatory Flexibility Analysis Required: Business

Government Levels Affected: State

Federalism: Yes

Energy Affected: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF26

View Related Documents

Title: Blood Initiative--Revisions to Labeling Requirements for Blood and Blood Components, Including Source Plasma; and Technical Amendment

Abstract: The Food and Drug Administration (FDA) is amending the regulations regarding container labels and instruction circulars for certain human blood and blood components, including Source Plasma, to be more consistent with current practices and to remove unnecessary or outdated requirements. This action is based on FDA's comprehensive review of the biologics regulations. It is also based on reports by the U.S. House of Representatives Committee on Government Reform and Oversight Subcommittee on House Resources and Intergovernmental Relations, the Government Accountability Office (previously, the General Accounting Office), and the Institute of Medicine, as well as on public comments. This action is intended to help ensure the continued safety of the blood supply and to help ensure consistency in container labeling. The rule will consolidate regulations applicable to labeling standards so that most labeling requirements for all blood and blood components, including Source Plasma, found previously in 21 CFR 606.121 and 21 CFR 640.70, can now be found in 21 CFR 606.121.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 606; 21 CFR 610; 21 CFR 640 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360d; 21 USC 360h to 360j; 21 USC 371; 21 USC 374; 21 USC 381; 42 USC 216; 42 USC 262 and 263; 42 USC 263a; 42 USC 264
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	07/30/2003	68 FR 44678
NPRM Comment Period End	10/28/2003	
Final Action	09/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Related RINs: Split From 0910-AB26

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF27

View Related Documents

Title: Infant Formula: Current Good Manufacturing Practices; Quality Control Procedures; Notification Requirements; Records and Reports; and Quality Factors

Abstract: The agency published a proposed rule on July 9, 1996, that would establish current good manufacturing practice regulations, quality control procedures, quality factors, notification requirements, and records and reports for the production of infant formula. This proposal was issued in response to the 1986 Amendments to the Infant Formula Act of 1980. On April 28, 2003, FDA reopened the comment period to update comments on the proposal. The comment period was extended on June 27, 2003, to end on August 26, 2003. The comment period was reopened on August 1, 2006, to end on September 15, 2006.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 106 and 107 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 350a; 21 USC 371; ...
Legal Deadline: None

Regulatory Plan:

Statement of Need: The Food and Drug Administration (FDA) is revising its infant formula regulations in 21 CFR Parts 106 and 107 to establish requirements for current good manufacturing practices (CGMP), including audits; to establish requirements for quality factors; and to amend FDA's quality control procedures, notification, and record and reporting requirements for infant formula. FDA is taking this action to improve the protection of infants who consume infant formula products.

Legal Basis: The Infant Formula Act of 1980 (the 1980 act) (Pub. L. 96-359) amended the Federal Food, Drug, and Cosmetic Act (the act) to include § 412 (21 U.S.C. 350a). This law is intended to improve protection of infants consuming infant formula products by establishing greater regulatory control over the formulation and production of infant formula. In 1982, FDA adopted infant formula recall procedures in subpart D of 21 CFR part 107 of its regulations (47 FR 18832, April 30, 1982), and infant formula quality control procedures in subpart B of 21 CFR Part 106 (47 FR 17016, April 20, 1982). In 1985, FDA further implemented the 1980 act by establishing subparts B, C, and D in 21 CFR Part 107 regarding the labeling of infant formula, exempt infant formulas, and nutrient requirements for infant formula, respectively (50 FR 1833, January 14, 1985; 50 FR 48183, November 22, 1985; and 50 FR 45106, October 30, 1985). In 1986, Congress, as part of the Anti-Drug Abuse Act of 1986 (PL 99-570) (the 1986 amendments), amended § 412 of the act to address concerns that had been expressed by Congress and consumers about the 1980 act and its implementation related to the sufficiency of quality control testing, CGMP, recordkeeping, and recall requirements. The 1986 amendments: (1) state that an infant formula is deemed to be adulterated if it fails to provide certain required nutrients, fails to meet quality factor requirements established by the Secretary (and, by delegation, FDA), or if it is not processed in compliance with the CGMP and quality control procedures established by the Secretary; (2) require that the Secretary issue regulations establishing requirements for quality factors and CGMP, including quality control procedures; (3) require that infant formula manufacturers regularly audit their operations to ensure that those operations comply with CGMP and quality control procedure regulations; (4) expand the circumstances in which firms must make a submission to the agency to include when there is a major change in an infant formula or a change that may affect whether the formula is adulterated; (5) specify the nutrient quality control testing that must be done on each batch of infant formula; (6) modify the infant formula recall requirements; and (7) give the Secretary authority to establish requirements for retention of records, including records necessary to demonstrate compliance with CGMP and quality control procedures. In 1989, the agency implemented the provisions on recalls (sections 412(f) and (g) of the act) by establishing subpart E in 21 CFR part 107 (54 FR 4006, January 27, 1989). In 1991, the agency implemented the provisions on record and record retention requirements by revising 21 CFR 106.100 (56 FR 66566, December 24, 1991). The agency has already promulgated regulations that respond to a number of the provisions of the 1986 amendments. The final rule would address additional provisions of these amendments.

Alternatives: The 1986 amendments require the Secretary (and, by delegation, FDA) to establish, by regulation, requirements for quality factors and CGMPs, including quality control procedures. Therefore, there are no alternatives to rulemaking.

Costs and Benefits: FDA estimates that the costs from the final rule to producers of infant formula would include first year and recurring costs (e.g., administrative costs, implementation of quality controls, records, audit plans and assurances of quality factors in new infant formulas). FDA anticipates that the primary benefits would be a reduced risk of illness due to Cronobacter sakazakii and Salmonella spp in infant formula. Additional benefits stem from the quality factors requirements that would assure the healthy growth of infants consuming infant formula. Monetized estimates of costs and benefits for this final rule are not available at this time. The analysis for the proposed rule estimated costs of less than $1 million per year. FDA was not able to quantify benefits in the analysis for the proposed rule.

Risks: Special controls for infant formula manufacturing are especially important because infant formula, particularly powdered

infant formula, is an ideal medium for bacterial growth and because infants are at high risk of foodborne illness because of their immature immune systems. In addition, quality factors are of critical need to assure that the infant formula supports healthy growth in the first months of life when infant formula may be an infant's sole source of nutrition. The provisions of this rule will address weaknesses in production that may allow contamination of infant formula, including, contamination with C. sakazakii and Salmonella spp which can lead to serious illness with devastating sequelae and/or death. The provisions would also assure that new infant formulas support healthy growth in infants.

Timetable:

Action	Date	FR Cite
NPRM	07/09/1996	61 FR 36154
NPRM Comment Period End	12/06/1996	
NPRM Comment Period Reopened	04/28/2003	68 FR 22341
NPRM Comment Period Extended	06/27/2003	68 FR 38247
NPRM Comment Period End	08/26/2003	
NPRM Comment Period Reopened	08/01/2006	71 FR 43392
NPRM Comment Period End	09/15/2006	
Final Action	10/00/2010	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: No

Federalism: No

Energy Affected: No

International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

Related RINs: Split From 0910-AA04

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF32

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Cough/Cold (Bronchodilator) Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses labeling for single ingredient bronchodilator products.

Priority: Routine and Frequent Agenda Stage of Rulemaking: Final Rule

Major: No Unfunded Mandates: No

CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM (Amendment--Ephedrine Single Ingredient)	07/13/2005	70 FR 40237
Final Action (Technical Amendment)	11/30/2007	72 FR 67639
Final Action (Amendment--Ephedrine Single Ingredient)	05/00/2010	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Local; State

Federalism: Yes

Related RINs: Split From 0910-AA01

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF33

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Cough/Cold (Combination) Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action finalizes cough/cold combination products containing oral bronchodilators and expectorants.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM (Amendment)	07/13/2005	70 FR 40232
Final Action (Technical Amendment)	03/19/2007	72 FR 12730
Final Action	09/00/2010	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF34

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Cough/Cold (Nasal Decongestant) Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses the ingredient

phenylpropanolamine.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Sinusitis Claim)	08/02/2004	69 FR 46119
NPRM (Phenylephrine Bitartrate)	11/02/2004	69 FR 63482
Final Action (Amendment) (Sinusitis Claim)	10/31/2005	70 FR 58974
NPRM (Phenylpropanolamine)	12/22/2005	70 FR 75988
Final Action (Phenylephrine Bitartrate)	08/01/2006	71 FR 83358
Final Action (Phenylpropanolamine)	09/00/2010	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AF35

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--External Analgesic Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The final action addresses the 2003 proposed rule on patches, plasters, and poultices. The proposed rule will address issues not addressed in previous rulemakings.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM (Amendment)	00/00/0000	
Final Action (GRASE dosage forms)	09/00/2010	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes

Related RINs: Split From 0910-AA01

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF36

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Internal Analgesic Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The first action addresses products labeled to relieve upset stomach associated with overindulgence in food and drink and to relieve symptoms associated with a hangover. The second action addresses products marketed for children under 2 years old and weight- and age-based dosing for children's products. The third action addresses combination products containing the analgesic acetaminophen or aspirin and sodium bicarbonate used as an antacid ingredient. The fourth action addresses other miscellaneous issues relating to internal analgesics. The last document finalizes the Internal Analgesic Products monograph.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371; 21 USC 374; 21 USC 379e
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Pediatric)	00/00/0000	
Final Action (Internal Analgesics)	00/00/0000	
NPRM (Amendment) (Overindulgence/Hangover)	00/00/0000	
NPRM (Amendment) (Combinations With Sodium Bicarbonate)	00/00/0000	
NPRM (Amendment) (Required Warnings and Other Labeling)	12/26/2006	71 FR 77314
NPRM Comment Period End	05/25/2007	
Final Action (Required Warnings and Other Labeling)	04/29/2009	74 FR 19385
Final Action (Correction)	06/30/2009	74 FR 31177
Final Action (Technical Amendment)	12/00/2009	
NPRM (Amendment) (Miscellaneous Issues)	09/00/2010	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF37

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Labeling of Drug Products for OTC Human Use

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses labeling for convenience (small) size OTC drug packages.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 358; 21 USC 360; 21 USC 371; 21 UCS 374; 21 USC 379e
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM (Convenience Sizes)	12/12/2006	71 FR 74474
Final Action	05/00/2010	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF42

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Skin Protectant Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The first action addresses skin protectant products used to treat fever blisters and cold sores. The second action identifies safe and effective skin protectant active ingredients to treat and prevent diaper rash.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action (Technical Amendments)	02/01/2008	73 FR 6014
Final Action (Aluminum Acetate) (Technical Amendment)	03/06/2009	74 FR 9759
Final Action (Diaper Rash)	06/00/2010	
Final Action (Fever Blisters/Cold Sores)	06/00/2010	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF47

View Related Documents

Title: Use of Materials Derived From Cattle in Human Food and Cosmetics

Abstract: On July 14, 2004, FDA issued an interim final rule (IFR), effective immediately, to prohibit the use of certain cattle material and to address the potential risk of bovine spongiform encephalopathy (BSE) in human food, including dietary supplements, and cosmetics. Prohibited cattle materials under the IFR include specified risk materials, small intestine of all cattle, material from nonambulatory disabled cattle, material from cattle not inspected and passed for human consumption, and mechanically separated (MS) beef. Specified risk materials are the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months and older; and the tonsils and distal ileum of the small intestine of all cattle. Prohibited cattle materials do not include tallow that contains no more than 0.15 percent hexane-insoluble impurities and tallow derivatives. This action minimizes human exposure to materials that scientific studies have demonstrated are highly likely to contain the BSE agent in cattle infected with the disease. Scientists believe that the human disease variant Creutzfeldt-Jakob disease (vCJD) is likely caused by the consumption of products contaminated with the agent that causes BSE. On September 7, 2005, FDA amended the IFR to permit the use of small intestine in human food and cosmetics if it is effectively removed from the distal ileum. The amendment also clarified that milk and milk products, hides, and tallow derivatives are not prohibited for use in human food and cosmetics. On April 17, 2008, FDA amended the IFR so that FDA may designate a country as not subject to certain BSE-related restrictions relating to prohibited cattle materials applicable to human food and cosmetics. Comments submitted in response to the July 14, 2004 IFR that were not addressed in the September 7, 2005 and April 17, 2008 amendments will be addressed in the final rule. The final rule also will respond to comments submitted following the September 7, 2005 and April 17, 2008 amendments.

Priority: Other Significant Agenda Stage of Rulemaking: Final Rule
Major: No Unfunded Mandates: No
CFR Citation: 21 CFR 189.5; 21 CFR 700.27 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 342; 21 USC 361; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Interim Final Rule Effective	07/14/2004	

Interim Final Rule	07/14/2004	69 FR 42256
Interim Final Rule Comment Period End	10/12/2004	
Interim Final Rule (Amendments)	09/07/2005	70 FR 53063
Interim Final Rule (Amendments) Effective	10/07/2005	
Interim Final Rule (Amendments) Comment Period End	11/07/2005	
Interim Final Rule (Amendments)	04/17/2008	73 FR 20785
Interim Final Rule (Amendments) Effective	07/16/2008	
Interim Final Rule (Amendments) Comment Period End	07/16/2008	
Final Action	10/00/2010	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: No

Federalism: No

Energy Affected: No

International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF54

View Related Documents

Title: Use of Materials Derived From Cattle in Medical Products Intended for Use in Humans and Drugs Intended for Use in Ruminants

Abstract: The regulation would prohibit the use of certain cattle material in the manufacture of medical products for humans and drugs for ruminants, and would require recordkeeping for products containing or manufactured with cattle materials to enable monitoring and enforcement of the prohibitions. The rule would prohibit the same cattle material that is prohibited in the previous FDA IFR that applies to foods and cosmetics. These include certain high risk tissues (e.g., brain, skull, eyes, spinal cord, trigeminal ganglia, parts of the vertebral column, and dorsal root ganglia) from cattle 30 months and older, tonsils and the distal ileum of cattle of any age, mechanically separated beef, material from nonambulatory disabled cattle, and material from cattle not inspected and passed for human consumption. The prohibitions would apply only to materials derived from animals slaughtered after the effective dates of the rule. The prohibitions would not apply to tallow that met a specified purity standard. The rule would provide criteria for deviations from the requirements based on a showing of safety or appropriate benefit-to-risk ratio.

Priority: Other Significant Agenda Stage of Rulemaking: Final Rule

Major: No Unfunded Mandates: No

CFR Citation: 21 CFR 211.116; 21 CFR 226.60; 21 CFR 300.200; 21 CFR 500.200; 21 CFR 530; 21 CFR 600.16; 21 CFR 895.102; 21 CFR 1271.465; 21 CFR 1271.470 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 and 352; 21 USC 355; 21 USC 360b; 21 USC 360f; 21 USC 360i; 21 USC 371; 21 USC 374; 21 USC 381; 42 USC 262; 42 USC 264; 42 USC 271

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	01/12/2007	72 FR 1582
NPRM Comment Period End	03/13/2007	
NPRM Comment Period Reopened	03/30/2007	
Final Action	05/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.
Related RINs: Merge with 0910-AF55

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF86

View Related Documents

Title: Medical Device Reporting; Electronic Submission Requirements

Abstract: The Food and Drug Administration (FDA) is proposing to amend its postmarket medical device reporting regulations to require that manufacturers, importers, and user facilities submit mandatory reports of medical device adverse events to the Agency in an electronic format that FDA can process, review, and archive. FDA is taking this action to improve the Agency's systems for collecting and analyzing postmarketing safety reports. The proposed change would help the Agency to more quickly review safety reports and identify emerging public health issues.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 803 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 352; 21 USC 360; 21 USC 360i; 21 USC 360j; 21 USC 371; 21 USC 374
Legal Deadline: None

Regulatory Plan:

Statement of Need: The final rule would require user facilities and medical device manufacturers and importers to submit medical device adverse event reports in electronic format instead of using a paper form. FDA is taking this action to improve its adverse event reporting program by enabling it to more quickly receive and process these reports.

Legal Basis: The Agency has legal authority under section 519 of the Federal Food, Drug, and Cosmetic Act to require adverse event reports. The proposed rule would require manufacturers, importers, and user facilities to change their procedures to send reports of medical device adverse events to FDA in electronic format instead of using a hard copy form.

Alternatives: The alternatives to this rulemaking include not updating the medical device reporting requirements and not requiring submission of this information in electronic format. For over 20 years, medical device manufacturers, importers, and user facilities have sent adverse event reports to FDA on paper forms. Processing paper forms is a time-consuming and expensive process. FDA believes this rulemaking is the preferable alternative.

Costs and Benefits: The principal benefit would be to public health because the increased speed in the processing and analysis of the more than 200,000 medical device reports currently submitted annually on paper. In addition, requiring electronic submission would reduce FDA annual operating costs by $1.25 million. The total one-time cost for modifying SOPs and establishing electronic submission capabilities is estimated to range from $58.6 million to $79.7 million. Annually recurring costs totaled $8.5 million and included maintenance of electronic submission capabilities, including renewing the electronic certificate, and for some firms the incremental cost to maintain high-speed internet access.

Risks: None

Timetable:

Action	Date	FR Cite
NPRM	08/21/2009	74 FR 42310
NPRM Comment Period End	11/19/2009	
Final Action	09/00/2010	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: No

Energy Affected: No

International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF93

View Related Documents

Title: Use of Ozone-Depleting Substances; Removal of Essential Use Designations [Flunisolide, Triamcinolone, Metaproterenol, Pirbuterol, Albuterol and Ipratropium in Combination, Cromolyn, and Nedocromil]

Abstract: Medical products using chlorofluorocarbons (CFCs) and other ozone-depleting substances may only be legally marketed if they are listed in 21 CFR part 2.125 as "essential uses." This final rule would remove the essential use designations after a specified date for metered-dose inhalers (MDIs) containing flunisolide, triamcinolone, metaproterenol, pirbuterol, albuterol and ipratropium in combination, cromolyn, and nedocromil. Under the provisions of this final rule, these MDIs would have to be removed from the market. This final rule is consistent with obligations under the Clean Air Act and the Montreal Protocol on Substances That Deplete the Ozone Layer.

Priority: Economically Significant

Agenda Stage of Rulemaking: Final Rule

Major: Yes

Unfunded Mandates: No

CFR Citation: 21 CFR 2.125 (Revision); 40 CFR 82.4; 40 CFR 82.64; 40 CFR 82.66 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 335; 21 USC 342; 21 USC 346a; 21 USC 348; 21 USC 351 and 352; 21 USC 355; 21 USC 360b; 21 USC 361 and 362; 21 USC 371 and 372; 21 USC 374; 42 USC 7671 et seq

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	06/11/2007	72 FR 32030
NPRM Comment Period End	09/10/2007	
Final Action	12/00/2009	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: No

Federalism: No

Energy Affected: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF96

View Related Documents

Title: Postmarketing Safety Reports for Human Drug and Biological Products: Electronic Submission Requirements

Abstract: The proposed rule would amend FDA's postmarketing safety reporting regulations for human drug and biological products (21 CFR part 310.305, 314.80, 314.98, 600.80, and 600.81) to require that safety reports submitted to the Agency by persons subject to mandatory reporting requirements be transmitted in an electronic format that FDA can process, review, and archive. FDA is taking this action to improve the Agency's systems for collecting and analyzing postmarketing safety reports. Under the proposed rule, required reports could be submitted using either direct submission or a Web-based form. The rule will allow the Agency to review safety reports more quickly, to identify emerging safety problems, and disseminate safety information more rapidly in support of FDA's public health mission. The proposed amendments would be a key element in harmonizing FDA's postmarketing safety reporting regulations with international and ICH standards for the electronic submission of safety information.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 310.305; 21 CFR 314.80; 21 CFR 314.98; 21 CFR 600.80 and 600.81 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355 to 355a; 21 USC 356 to 356c; 21 USC 360; 21 USC 371; 21 USC 374; 21 USC 375; 21 USC 379aa; 21 USC 381; 42 USC 241; 42 USC 262; 42 USC 264; ...
Legal Deadline: None

Timetable:

Action	Date	FR Cite
ANPRM	11/05/1998	63 FR 59746
ANPRM Comment Period End	02/03/1999	
NPRM	08/21/2009	74 FR 42184
NPRM Comment Period End	11/19/2009	
Final Action	09/00/2010	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Federalism: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG00

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Acne Drug Products Containing Benzoyl Peroxide

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action will address acne drug products containing benzoyl peroxide.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360 to 360a; 21 USC 371 to 371a
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	12/00/2009	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AG13

View Related Documents

Title: Premarketing Safety Reporting Requirements for Human Drug and Biological Products

Abstract: The final rule would amend the premarketing safety reporting requirements for human drugs and biological products to codify the Agency's expectations for timely acquisition, evaluation, and submission of relevant and useful safety information, to improve the overall quality of safety reporting, to implement internationally consistent definitions, to subject bioavailability and bioequivalence studies to safety reporting requirements, and to make other minor revisions. These revisions were proposed as part of a single rulemaking (68 FR 12406) to clarify and revise both premarketing and postmarketing safety reporting requirements for human drug and biological products. FDA plans to finalize the premarket and postmarket safety reporting requirements in separate final rules.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 312; 21 CFR 320 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 216; 42 USC 241; 42 USC 242a; 42 USC 262 and 263; 42 USC 263a to 263n; 42 USC 264; 42 USC 300aa; 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360b to 360j; 21 USC 361a; 21 USC 371; 21 USC 374; 21 USC 375; 21 USC 379e; 21 USC 381
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/14/2003	68 FR 12406
NPRM Comment Period Extended	06/18/2003	
NPRM Comment Period End	07/14/2003	
NPRM Comment Period Extended End	10/14/2003	
Final Action	03/00/2010	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: Business
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG33

View Related Documents

Title: Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents

Abstract: This rule establishes regulations restricting the sale and distribution of cigarettes and smokeless tobacco to children and adolescents, implementing section 102 of the Family Smoking Prevention and Tobacco Control Act (FSPTCA). FSPTCA sections 102 and 6(c)(1) require the Secretary to publish, within 270 days of enactment, a final rule regarding cigarettes and smokeless tobacco. This final rule must be identical, except for several changes identified in section 102(a)(2) of FSPTCA, to part 897 of the regulations promulgated by the Secretary of HHS in the August 28, 1996 issue of the Federal Register (61 FR 44396). This final rule prohibits the sale of cigarettes and smokeless tobacco to individuals under the age of 18 and requires manufacturers, distributors, and retailers to comply with certain conditions regarding access to, and promotion of, these products. Among other things, the final rule requires retailers to verify a purchaser's age by photographic identification. It also prohibits, with limited exception, free samples and prohibits the sale of these products through vending machines and self-service displays except in facilities where individuals under the age of 18 are not present or permitted at any time. The rule also limits the advertising and labeling to which children and adolescents are exposed. The rule accomplishes this by generally restricting advertising to which children and adolescents are exposed to a black-and-white, text-only format. The rule also prohibits the sale or distribution of brand-identified promotional, non-tobacco items such as hats and tee shirts. Furthermore, the rule prohibits sponsorship of sporting and other events, teams, and entries in a brand name of a tobacco product, but permits such sponsorship in a corporate name.

Priority: Economically Significant
Agenda Stage of Rulemaking: Final Rule
Major: Yes
Unfunded Mandates: State, Local, Or Tribal Governments; Private Sector

CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 301 et seq., The Federal Food, Drug, and Cosmetic Act; PL 111-31, Family Smoking Prevention and Tobacco Control Act

Legal Deadline: Family Smoking Prevention and Tobacco Control Act §§ 6(c)(1) and 102(a)(1) require publication of this final rule within 270 days of enactment.

Action	Source	Description	Date
Other	Statutory	Public Law 111-30 sections 6(c)(1) and 102(a)(1)	03/22/2010

Regulatory Plan:

Statement of Need: FDA is issuing this regulation as required in section 102 of FSPTCA.

Legal Basis: The legal authority to issue this regulation includes section 102 of FSPTCA.

Alternatives: FDA's statutory requirement to issue this rule, in its current form, does not provide for the consideration of any alternatives.

Costs and Benefits: Congress has recognized that tobacco use is the foremost preventable cause of premature death in America. It causes over 400,000 deaths in the United States each year, and approximately 8,600,000 Americans have chronic illnesses related to smoking. Based on FDA's prior analysis of a similar rule, implementing nearly identical provisions (61 FR 44396), the Food and Drug Administration (FDA) believes this rulemaking will have a significant economic impact. Costs

associated with this rulemaking will include one-time costs to manufacturers to remove prohibited point-of-sale promotional items and self-service displays. Most costs to retail establishments are attributable to the new labor costs associated with the self-service restrictions, costs for training employees to verify customer ages, for routinely checking I.D.'s of young purchasers. There are also costs seen by consumers in delay in checkout lines. Distributional and transitional costs are also expected.

Risks: Congress has found that these regulations will directly and materially advance the Federal Government's substantial interest in reducing the number of children and adolescents who use cigarettes and smokeless tobacco and in preventing the life-threatening health consequences associated with tobacco use. An overwhelming majority of Americans who use tobacco products begin using such products while they are minors and become addicted to the nicotine in those products before reaching the age of 18. Tobacco advertising and promotion play a crucial role in the decision of these minors to begin using tobacco products. Less restrictive and less comprehensive approaches have not and will not be effective in reducing the problems addressed by such regulations. The reasonable restrictions on the advertising and promotion of tobacco products contained in such regulations will lead to a significant decrease in the number of minors using and becoming addicted to those products.

Timetable:

Action	Date	FR Cite
Final Rule	03/00/2010	

Regulatory Flexibility Analysis Required: Business

Government Levels Affected: Federal; Local; State; Tribal

Federalism: Yes

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)

RIN: 0910-AB88

View Related Documents

Title: Current Good Manufacturing Practice in Manufacturing, Packing, Labeling, or Holding Operations for Dietary Supplements

Abstract: The Food and Drug Administration published a final rule in the Federal Register of June 25, 2007 (72 FR 34752), on current good manufacturing practice (CGMP) regulations for dietary supplements. FDA also published an Interim Final Rule in the same Federal Register (72 FR 34959) that provided a procedure for requesting an exemption from the final rule requirement that the manufacturer conduct at least one appropriate test or examination to verify the identity of any component that is a dietary ingredient. This IFR allows for submission to, and review by, FDA of an alternative to the required 100 percent identity testing of components that are dietary ingredients, provided certain conditions are met. This IFR also establishes a requirement for retention of records relating to the FDA's response to an exemption request.

Priority: Economically Significant

Agenda Stage of Rulemaking: Long-term Action

Major: Yes

Unfunded Mandates: Private Sector

CFR Citation: 21 CFR 111 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 321; 21 USC 342 and 343; 21 USC 348; 21 USC 371; 21 USC 374; 21 USC 381; 21 USC 393; 42 USC 264

Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
ANPRM	02/06/1997	62 FR 5700
ANPRM Comment Period End	06/06/1997	
NPRM	03/13/2003	68 FR 12157
NPRM Comment Period End	08/11/2003	
Interim Final Rule	06/25/2007	72 FR 34959

Final Action	06/25/2007	72 FR 34752
Interim Final Rule Comment Period End	10/24/2007	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Undetermined
Federalism: No
Energy Affected: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AC50

View Related Documents

Title: Food Labeling: Trans Fatty Acids in Nutrition Labeling: Consumer Research To Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements

Abstract: The Food and Drug Administration issued an Advance Notice of Proposed Rulemaking on July 11, 2003 (68 FR 41507), to solicit information and data that potentially could be used to establish new nutrient content claims about trans fatty acids; to establish qualifying criteria for trans fat in current nutrient content claims for saturated fat and cholesterol, lean and extra lean claims, and health claims that contain a message about cholesterol-raising lipids; and, in addition, to establish disclosure and disqualifying criteria to help consumers make heart-healthy food choices. The Agency also requested comments on whether it should consider statements about trans fat, either alone or in combination with saturated fat and cholesterol, as a footnote in the Nutrition Facts panel or as a disclosure statement in conjunction with claims to enhance consumers' understanding about such cholesterol-raising lipids and how to use the information to make healthy food choices. Information and data obtained from comments and from consumer studies that will be conducted by FDA also may be used to help draft a proposed rule that would establish criteria for certain nutrient content or health claims or require the use of a footnote, or other labeling approach, about one or more cholesterol-raising lipids in the Nutrition Facts panel to assist consumers in maintaining healthy dietary practices.

Priority: Other Significant Agenda Stage of Rulemaking: Long-term Action
Major: No Unfunded Mandates: No
CFR Citation: 21 CFR 101 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 343; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	
ANPRM	07/11/2003	68 FR 41507
ANPRM Comment Period End	10/09/2003	
ANPRM Comment Period Reopened for 45 days	03/01/2004	69 FR 9559
ANPRM Comment Period Extended for Additional 60 days	04/19/2004	69 FR 20838
ANPRM Comment Period End	06/18/2004	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Federal
Federalism: Yes
Energy Affected: No

International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

Related RINs: Related to 0910-AB66

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AC54

View Related Documents

Title: Food Standards: General Principles and Food Standards Modernization

Abstract: In 1995, the FDA and FSIS reviewed their regulatory procedures and requirements for food standards to determine whether any were still needed, and if so, which ones should be modified or streamlined. To request public comment to assist them in their review of the need for food standards, both Agencies published advance notices of proposed rulemaking (ANPRMs) on food standards in December 1995 (60 FR 47453 and 60 FR 67492). These ANPRMs discussed the Agencies' regulations and policy governing food standards, the history of food standards, and the possible need to revise the food standards. Several comments in response to the ANPRMs recommended that the Agencies establish general principles or a fundamental philosophy for reviewing food standards and revising them. The Agencies agreed with these comments and determined that it would be appropriate to develop general principles for reviewing and revising food standards regulations. The Agencies also agreed with the comments that stated that the Agencies should work in concert to develop consistent food standards regulations. FDA and FSIS proposed a set of general principles that define how modern food standards should be structured (70 FR 29214, May 20, 2005). If this proposed rule is adopted, FDA and FSIS will require that a citizen petition for establishing, revising, or eliminating a food standard in 21 CFR parts 130 to 169 and 9 CFR part 319 be submitted in accordance with the general principles. Conversely, the Agencies may find deficient a petition to establish, revise, or eliminate a food standard that does not follow these general principles.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 130.5 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 336; 21 USC 341; 21 USC 343; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
ANPRM	12/29/1995	60 FR 67492
ANPRM Comment Period End	04/29/1996	
NPRM	05/20/2005	70 FR 29214
NPRM Comment Period End	08/18/2005	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Undetermined
Small Entities Affected: No
Federalism: No
Energy Affected: No
Related RINs: Related to 0583-AC72
Related Agencies: Joint: FSIS

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF08

View Related Documents

Title: Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; Revision of Certain Labeling Controls

Abstract: The proposed rule would amend the packaging and labeling control provisions of the current good manufacturing practice regulations for human and veterinary drug products by limiting the application of special control procedures for the use of cut labeling to immediate container labels, individual unit cartons, or multiunit cartons containing immediate containers that are not packaged in individual unit cartons. The proposal would also permit the use of any automated technique, including differentiation by labeling size and shape, that physically prevents incorrect labeling from being processed by labeling and packaging equipment when cut labeling is used.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: 21 CFR 211.122 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 351
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM	07/29/1997	62 FR 40489
NPRM Comment Period End	10/27/1997	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Small Entities Affected: Business
Federalism: Undetermined
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF22

View Related Documents

Title: Food Labeling; Prominence of Calories

Abstract: In response to the Report of the Working Group on Obesity (OWG) that FDA issued on March 12, 2004, the Agency issued on April 4, 2005, an advance notice of proposed rulemaking (ANPRM) in its efforts to combat the Nation's obesity problem. The ANPRM requested comments on ways to give more prominence to calories on the food label.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 101.9 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 343; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	
ANPRM	04/04/2005	70 FR 17008
ANPRM Comment Period End	06/20/2005	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Energy Affected: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)

RIN: 0910-AF23

View Related Documents

Title: Food Labeling; Serving Sizes of Products That Can Reasonably Be Consumed at One Eating Occasion; Updating of Reference Amounts Customarily Consumed; Approaches for Recommending Smaller Portion Sizes

Abstract: In response to the Report of the Working Group on Obesity that FDA issued on March 12, 2004, the Agency issued on April 4, 2005, an advance notice of proposed rulemaking (ANPRM) in its efforts to combat the Nation's obesity problem. The ANPRM requested comments on possible changes to the Agency's nutrition labeling regulations on serving size and comments on other approaches for promoting consumption of smaller portion sizes.

Priority: Other Significant

Agenda Stage of Rulemaking: Long-term Action

Major: No

Unfunded Mandates: No

CFR Citation: 21 CFR 101.9; 21 CFR 101.12; 21 CFR 101.60(b) (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 321; 21 USC 343; 21 USC 371

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	
ANPRM	04/04/2005	70 FR 17010
ANPRM Comment Period End	06/20/2005	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Energy Affected: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF25

View Related Documents

Title: Blood Initiative--Requirements for Human Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use

Abstract: The Food and Drug Administration (FDA) is amending the biologics regulations, particularly those related to blood donor eligibility, by removing, revising, or updating specific regulations applicable to blood, blood components, source plasma, and source leukocytes to be more consistent with current practices and to remove unnecessary or outdated requirements. This action is based on FDA's comprehensive review of the biologics regulations. It is also responsive to reports by the U.S. House of Representatives Committee on Government Reform and Oversight Subcommittee on House Resources and Intergovernmental Relations, the Government Accountability Office (previously, the General Accounting Office), and the Institute of Medicine, and to public comments. These actions are intended to help ensure the continued safety of the Nation's blood supply.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 606; 21 CFR 610; 21 CFR 630; 21 CFR 640; 21 CFR 660; 21 CFR 820; 21 CFR 1270 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360c to 360e; 21 USC 360h to 360j; 21 USC 360l; 21 USC 371; 21 USC 372; 21 USC 374; 21 USC 381; 21 USC 383; 42 USC 216; 42 USC 243; 42 USC 262 and 263; 42 USC 263a; 42 USC 264; 42 USC 271
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM	11/08/2007	72 FR 63416
NPRM Comment Period Extended	01/11/2008	73 FR 1983
NPRM Comment Period End	02/06/2008	
NPRM Comment Period End	08/04/2008	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
Related RINs: Split From 0910-AB26

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF39

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Ophthalmic Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action finalizes the monograph for

emergency first aid eyewash drug products.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action (Amendment) (Emergency First Aid Eyewashes)	00/00/0000	
NPRM (Amendment) (Emergency First Aid Eyewashes)	02/19/2003	68 FR 7917

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AF40

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Oral Health Care Products
Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The NPRM and final action will address oral health care products used to reduce or prevent dental plaque and gingivitis.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360 to 360a; 21 USC 371 to 371a
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM (Plaque Gingivitis)	00/00/0000	
ANPRM (Plaque Gingivitis)	05/29/2003	68 FR 32232
ANPRM Comment Period End	08/27/2003	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
Related RINs: Split From 0910-AA01
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF51

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Overindulgence in Food and Drink Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses products containing bismuth subsalicylate for relief of symptoms of upset stomach due to overindulgence resulting from food and drink.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM (Amendment)	01/05/2005	70 FR 741

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF52

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Antacid Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. One action addresses the labeling of products containing sodium bicarbonate as an active ingredient. The other action addresses the use of antacids to relieve upset stomach associated with overindulgence in food and drink.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action (Overindulgence Labeling)	00/00/0000	
Final Action (Sodium Bicarbonate Labeling)	00/00/0000	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AF53

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Skin Bleaching Products
Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses skin bleaching drug products containing hydroquinone.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM	08/29/2006	71 FR 51146
NPRM Comment Period End	12/27/2006	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF56

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Stimulant Drug Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses the use of stimulant active ingredients to relieve symptoms associated with a hangover.

Priority: Routine and Frequent Agenda Stage of Rulemaking: Long-term Action
Major: No Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM (Amendment) (Hangover)	00/00/0000	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Local; State
Federalism: Yes

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF61

View Related Documents

Title: Label Requirement for Food That Has Been Refused Admission Into the United States

Abstract: The final rule will require owners or consignees to label imported food that is refused entry into the United States. The label will read, "UNITED STATES: REFUSED ENTRY." The proposal describes the label's characteristics (such as its size) and processes for verifying that the label has been affixed properly. We are taking this action to prevent the introduction of unsafe food into the United States, to facilitate the examination of imported food, and to implement section 308 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Pub. L. 107-188).

Priority: Other Significant Agenda Stage of Rulemaking: Long-term Action
Major: No Unfunded Mandates: No
CFR Citation: 21 CFR 1.98 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 15 USC 1453 to 1455; 21 USC 321; 21 USC 342 and 343; 21 USC 371; 21 USC 374; 21 USC 381; 42 USC 216; 42 USC 264
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM	09/18/2008	73 FR 54106
NPRM Comment Period End	12/02/2008	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Undetermined
Federalism: No
Energy Affected: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF63

View Related Documents

Title: Over-the-Counter Antidiarrheal Drug Products
Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. These actions address new labeling for antidiarrheal drug products.

Priority: Routine and Frequent Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action (New Labeling)	00/00/0000	
NPRM (New Labeling)	00/00/0000	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Local; State
Federalism: Yes
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF69

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Topical Antimicrobial Drug Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. The first action addresses health care products. The second action addresses food handler products. The third action addresses testing requirements. The fourth action addresses consumer products. The final actions listed will address the healthcare, consumer, and first aid antiseptic drug products respectively.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action (First Aid Antiseptic)	00/00/0000	
Final Action (Consumer)	00/00/0000	
NPRM (Testing)	00/00/0000	
Final Action (Healthcare)	00/00/0000	
NPRM (Food Handlers)	00/00/0000	
NPRM (Healthcare)	06/17/1994	59 FR 31402
NPRM (Consumer)	12/00/2010	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF70

View Related Documents

Title: Over-the-Counter (OTC) Drug Review--Urinary Analgesic Drug Products

Abstract: The OTC drug review establishes conditions under which OTC drugs are considered generally recognized as safe and effective and not misbranded. After a final monograph (i.e., final rule) is issued, only OTC drugs meeting the conditions of the monograph, or having an approved new drug application, may be legally marketed. This action addresses the products used for urinary pain relief.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal

Regulations)

Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM (Urinary Analgesic)	00/00/0000	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Local; State

Federalism: Yes

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF81

View Related Documents

Title: Current Good Manufacturing Practice for Combination Products

Abstract: The proposed rule would clarify and codify the current good manufacturing practice (cGMP) requirements for combination products (combinations of a drug, device, and/or biological product). The proposed rule is intended to ensure consistency and appropriateness in the regulation of combination products. The proposed rule would provide a flexible, quality management regulatory framework that recognizes that, in most instances, for combination products, a properly implemented quality system program under one set of medical product cGMP regulations will meet the requirements of another set (e.g., application of cGMPs for finished pharmaceuticals in 21 CFR parts 210 and 211 will generally meet the requirements of the device quality system regulations in 21 CFR part 820). It would allow manufacturers the flexibility to implement either the drug CGMP or device quality system regulation if both would apply to their manufacture of the combination product, provided that they also incorporate select, key provisions from the other set of these regulations. It would avoid the necessity to fully implement both sets of cGMP regulations when manufacturing combination products.

Priority: Other Significant Agenda Stage of Rulemaking: Long-term Action

Major: No Unfunded Mandates: No

CFR Citation: 21 CFR 4, subchapter A (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360c to 360f; 21 USC 360h to 360j; 21 USC 360l; 21 USC 360hh to 360ss; 21 USC 360aaa to 360bbb; 21 USC 371a; 21 USC 372 to 374; 21 USC 379e; 21 USC 381; 21 USC 394; 42 USC 216; 42 USC 262; 42 USC 263a; 42 USC 264; 42 USC 271

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/23/2009	74 FR 48423
NPRM Extension of Comment Period	11/10/2009	
Final Action	08/00/2011	

Regulatory Flexibility Analysis Required: No Government Levels Affected: State

Small Entities Affected: Business Federalism: Yes

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF90

View Related Documents

Title: Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile

Abstract: FDA issued regulations to permit FDA Center Directors to grant an exception or alternative to certain regulatory labeling provisions applicable to human drugs, biological products, or medical devices that are or will be included in the Strategic National Stockpile (SNS). Under this rule, the appropriate FDA Center Director may grant an exception or alternative to such labeling requirements if he or she determines that compliance with such requirements could adversely affect the safety, effectiveness, or availability of specified lots, batches, or other units of human drugs, biological products, or medical devices that are or will be included in the SNS. A grant of an exception or alternative under these regulations will include any safeguards or conditions deemed appropriate by the FDA Center Director to ensure that the labeling of such products includes information for the safe and effective use of the products given their anticipated circumstances of use. This rule will facilitate the safety, effectiveness, and availability of appropriate medical countermeasures in the event of a public health emergency.

Priority: Other Significant Agenda Stage of Rulemaking: Long-term Action
Major: No Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 312; 21 CFR 314; 21 CFR 601; 21 CFR 610; 21 CFR 801; 21 CFR 807; 21 CFR 809; 21 CFR 812; 21 CFR 814 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 15 USC 1451 to 1561; 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355 and 356; 21 USC 358; 21 USC 360; 21 USC 371 to 375; 21 USC 379; 21 USC 381 and 382; 21 USC 393; 42 USC 216; 42 USC 241; 42 USC 262 to 264; 42 USC 271
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
Interim Final Rule	12/28/2007	72 FR 73589
Interim Final Rule Comment Period End	03/27/2008	

Regulatory Flexibility Analysis Required: No Government Levels Affected: Federal; State
Federalism: Yes
Energy Affected: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF95

View Related Documents

Title: Status of Certain Additional Over-the-Counter Drug Category II Active Ingredients

Abstract: The Food and Drug Administration (FDA) is proposing that certain ingredients in over-the-counter (OTC) drug products are not generally recognized as safe and effective or are misbranded. FDA is issuing this proposed rule because we did not receive any data and information on these ingredients in response to our request on December 31, 2003 (68 FR 75585). This proposed rule is part of FDA's ongoing review of OTC drug products.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 201; 21 CFR 310; 21 CFR 330 to 358 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321p; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM	06/19/2008	73 FR 34895
NPRM Comment Period End	09/17/2008	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: Yes

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AG30

View Related Documents

Title: Sunlamp Products; Proposed Amendment to the Performance Standard

Abstract: The Food and Drug Aministration's (FDA's) Center for Devices and Radiological Health (CDRH) intends to amend its standard for sunlamp products (21 CFR 1040.20). The sunlamp standard was promulgated in 1979 and FDA has not issued any amendments since 1985. CDRH issued two “Policy Letters” in 1985 and 1986 outlining FDA policy and providing a recommended exposure schedule. In 1999, FDA published an advanced notice of proposed rulemaking (ANPRM) that sought input on several proposed changes to the FDA performance standard for sunlamp products. The agency received 27 comments to the ANPRM. A summary is available on request. FDA plans to update the performance standard for sunlamp products to improve safety, reflect new scientific information, and work towards harmonization with international standards. FDA scientists have participated in amendments to the International Electrotechnical Commission's (IEC) international standard, IEC 60335-2-27, over the past 10 years. There are many elements of the IEC standard which FDA is considering adopting in our standard. Adopting specific elements of the IEC standard by reference would allow the agency to take advantage of the expertise of the international committees involved in the modernization of the international standard, and thus save agency resources. FDA also plans to include changes to the required warning label.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 1040.20 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Not Yet Determined
Legal Deadline: None

Timetable:

Action	Date	FR Cite

NPRM	12/00/2010	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined
Energy Affected: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG31

View Related Documents

Title: Unique Device Identification

Abstract: The Food and Drug Administration Amendments Act of 2007, amended the Food, Drug, and Cosmetic Act by adding section 519(f), 21 USC 360i(f). This section requires FDA to promulgate regulations establishing a unique identification system for medical devices requiring the label of medical devices to bear a unique identifier, unless FDA specifies an alternative placement or provides for exceptions. The unique identifier must adequately identify the device through distribution and use, and may include information on the lot or serial number.

Priority: Economically Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Not Yet Determined
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined
Energy Affected: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AC07

View Related Documents

Title: Additional Safeguards for Children in Clinical Investigations

Abstract: The final rule will finalize the interim final rule that published in April 2001, providing additional protections for children involved as subjects in clinical investigations of FDA-regulated products, as required by the Children's Health Act of 2000.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No

CFR Citation: 21 CFR 50; 21 CFR 56 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 21 USC 321; 21 USC 343; 21 USC 346 to 346a; 21 USC 348; 21 USC 350a and 350b; 21 USC 351 to 353; 21 USC 355; 21 USC 360; 21 USC 360c to 360f; 21 USC 360h to 360j; 21 USC 371; 21 USC 379e; 21 USC 381; 41 USC 216; 41 USC 241; 41 USC 262; 41 USC 263b to 263n

Legal Deadline: None

Timetable:

Action	Date	FR Cite
Interim Final Rule	04/24/2001	66 FR 20589
Interim Final Rule Comment Period End	07/23/2001	
Withdrawn From the Unified Agenda	10/21/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AC14

View Related Documents

Title: Prevention of Salmonella Enteritidis in Shell Eggs

Abstract: Publication of this final rule was an action item in the Food Protection Plan announced by the Department of Health and Human Services (HHS) in November 2007. In July 1999, the Food and Drug Administration (FDA) and the Food Safety Inspection Service (FSIS) committed to developing an action plan to address the presence of Salmonella Enteritidis (SE) in shell eggs and egg products using a farm-to-table approach. FDA and FSIS held a public meeting on August 26, 1999, to obtain stakeholder input on the draft goals, as well as to further develop the objectives and action items for the action plan. The Egg Safety Action Plan was announced on December 11, 1999. The goal of the Action Plan is to reduce egg-related SE illnesses. The Egg Safety Action Plan consists of eight objectives covering all stages of the farm-to-table continuum as well as support functions. On March 30, 2000 (Columbus, OH), April 6, 2000 (Sacramento, CA), and July 31, 2000 (Washington, DC), joint public meetings were held by FDA and FSIS to solicit and discuss information related to the implementation of the objectives in the Egg Safety Action Plan. On September 22, 2004, FDA published a proposed rule that would require egg safety measures to prevent the contamination of shell eggs with SE during egg production. The proposal also solicited comment on whether recordkeeping requirements should include a written SE prevention plan and records for compliance with the SE prevention measures, and whether safe egg handling and preparation practices should be mandated for retail establishments that specifically serve a highly susceptible population (e.g., nursing homes, hospitals, day care centers). The proposed egg production SE prevention measures included: (1) Provisions for procurement of chicks and pullets; (2) a biosecurity program; (3) a rodent and pest control program; (4) cleaning and disinfection of poultry houses that have had an environmental or egg test positive for SE; (5) egg testing when an environmental test is positive; and (6) refrigerated storage of eggs held at the farm.

Additionally, to verify that the measures have been effective, the rule proposes that producers test the poultry house environment for SE. If the environmental test is positive, eggs from that environment must be tested for SE, and if the egg test is positive, the eggs must be diverted to egg products processing or a treatment process that achieves at least a five-log destruction of SE. The proposed rule was a step in a broader farm-to-table egg safety effort that includes FDA's requirements for safe handling statements on egg cartons, and refrigerated storage of shell eggs at retail, and egg safety education for consumers and retail establishments. The rule had a 90-day comment period, which ended December 21, 2004. To discuss the proposed rule and solicit comments from interested stakeholders, FDA held three public meetings: October 28, 2004, in College Park, MD; November 9, 2004, in Chicago, IL; and November 16, 2004, in Los Angeles, CA. The comment period was reopened until July 25, 2005, to solicit further comment and information on industry practices and programs that prevent SE-monitored chicks from becoming infected by SE during the period of pullet rearing until placement into laying hen houses. On July 9, 2009, FDA published the final rule that requires shell egg producers to implement measures to prevent SE from contaminating eggs on the farm and from further growth during storage and transportation, and requires these producers to maintain records concerning their compliance with the rule and to register with FDA. FDA took this action because SE is among the leading bacterial causes of foodborne illness in the United States, and shell eggs are a primary source of human SE infections. The final rule will reduce SE-associated illnesses and deaths by reducing the risk that shell eggs are contaminated with SE. Egg producers with 50,000 or more laying hens have 12 months to comply with the final rule, as do persons who must comply with only the refrigeration requirements. Producers with fewer than 50,000 but at least 3,000 laying hens have 36 months to comply. Producers with fewer than 3,000 laying hens and those who sell all of their eggs directly to consumers are exempt from the rule. FDA is developing guidance documents and will hold public meetings this year to help ensure covered persons understand how to comply with the final rule.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
Unfunded Mandates: Private Sector
CFR Citation: 21 CFR 16; 21 CFR 116; 21 CFR 118 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 342; 21 USC 371; 21 USC 381; 21 USC 393; 42 USC 243; 42 USC 264; 42 USC 271; ...
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/22/2004	69 FR 56824
NPRM Comment Period End	12/21/2004	
NPRM Reopened Comment Period End	06/09/2005	70 FR 24490
NPRM Extension of Reopened Comment Period End	07/25/2005	70 FR 33404
Final Action	07/09/2009	74 FR 33030

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: State
Federalism: Yes
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AF13

View Related Documents

Title: Charging for Investigational Drugs Under an Investigational New Drug Application

Abstract: On August 13, 2009 (74 FR 40872), FDA published a final rule amending FDA's investigational new drug regulations concerning charging for investigational drugs. The rule clarifies the circumstances in which charging for an

investigational drug in a clinical trial is appropriate, sets forth criteria for charging for an investigational drug for the different types of treatment uses described in the Agency's rule on expanded access to investigational drugs for treatment use, and clarifies what costs can be recovered for an investigational drug.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 312.7 and 312.8 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 356; 21 USC 371; 21 USC 381 to 383; 21 USC 393; 42 USC 262
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/14/2006	71 FR 75168
NPRM Comment Period End	03/14/2007	
Final Action	08/13/2009	74 FR 40872

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AF14

View Related Documents

Title: Expanded Access to Investigational Drugs for Treatment Use
Abstract: FDA published a final rule in the Federal Register of August 13, 2009 (74 FR 40900), amending the regulations governing investigational new drugs to describe the ways patients my obtain investigational drugs for treatment use under expanded access programs. Under the rule, the use of investigational drugs is available to: (1) Individual patients, including in emergencies; (2) intermediate-size patient populations; and (3) larger populations under a treatment protocol or treatment IND.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 312.42; 21 CFR 312.300; 21 CFR 312.305; 21 CFR 312.310; 21 CFR 312.315; 21 CFR 312.320 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 331; 21 USC 351 to 353; 21 USC 355; 21 USC 360bbb; 21 USC 371; 42 USC 262
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/14/2006	71 FR 75147
NPRM Comment Period End	03/14/2007	
Final Action	08/13/2009	74 FR 40900

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Organizations
Federalism: No

Energy Affected: No

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF28

View Related Documents

Title: Infant Formula Quality Factors

Abstract: The Agency published a proposed rule on July 9, 1996, that would establish current good manufacturing practice regulations, quality control procedures, quality factors, notification requirements, and records and reports for the production of infant formula. This proposal was issued in response to the 1986 amendments to the Infant Formula Act of 1980. On April 28, 2003, FDA reopened the comment period to update comments on the proposal. The comment period was extended on June 27, 2003, to end on August 26, 2003. The comment period was reopened on August 1, 2006, to end on September 15, 2006.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 106 and 107 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 350a; 21 USC 371; ...
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	07/09/1996	61 FR 36154
NPRM Comment Period End	12/06/1996	
NPRM Comment Period Reopened	04/28/2003	68 FR 22341
NPRM Comment Period Extended	06/27/2003	68 FR 38247
NPRM Comment Period End	08/26/2003	
NPRM Comment Period Reopened	08/01/2006	71 FR 43392
NPRM Comment Period End	09/15/2006	
Merged With 0910-AF27	09/24/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.
Related RINs: Split From 0910-AA04

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AF46

View Related Documents

Title: Substances Prohibited From Use in Animal Food or Feed to Prevent the Transmission of Bovine Spongiform Encephalopathy

Abstract: On October 6, 2005, the Food and Drug Administration (FDA) proposed to amend its regulations to prohibit the use of certain cattle origin materials in the food or feed of all animals to further strengthen existing safeguards designed to help prevent the spread of bovine spongiform encephalopathy (BSE) in U.S. cattle. The discovery of a BSE-positive dairy cow in December 2003 has caused FDA to review its policies for prevention of BSE, which resulted in this rulemaking. On April 28, 2008, FDA published a final rule prohibiting the use of certain cattle origin materials in the food and feed of all animals. On October 23, 2008 FDA corrected the final rule on BSE that appeared in the Federal Register of April 25, 2008 (73 FR 22719-22758). The final rule was inadvertently published with incorrect dollar amounts in two separate areas: the summary of economic impacts and the paperwork burden table.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
Unfunded Mandates: No
CFR Citation: 21 CFR 589.2001 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 342; 21 USC 343; 21 USC 348; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
ANPRM	07/14/2004	69 FR 42288
ANPRM Comment Period End	08/13/2004	
NPRM	10/06/2005	70 FR 58569
NPRM Comment Period End	12/20/2005	
Final Rule	04/25/2008	73 FR 22720
Final Rule-Correction	10/23/2008	73 FR 63072
Final Rule Effective	04/27/2009	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: No
Federalism: No
International Impacts: This regulatory action will be likely to have international trade and investment effects, or otherwise be of international interest.

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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AG03

View Related Documents

Title: Defining "Small Numbers of Animals" for Minor Use Designation

Abstract: The designation provision of the Minor Use and Minor Species Animal Health Act of 2004 (MUMS Act) (21 USC 360ccc-2) provides incentives to animal drug sponsors to encourage development and approval of drugs for minor species and for minor uses in major animal species. Congress provided a statutory definition of “minor use” that relied on the phrase "small numbers of animals" to characterize such use (21 USC 321(pp)). At this time, FDA is amending 21 CFR part 516 (the implementing regulations of the MUMS Act) to further define “minor use” by defining a specific "small number of animals" for each of the seven major animal species, to be used in determining whether any particular intended use in a major species is a minor use.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 516 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 321; 21 USC 360ccc; 21 USC 360ccc-1; 21 USC 360ccc-2; 21 USC 371
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/18/2008	73 FR 14411
NPRM Comment Period End	07/16/2008	
Final Action	08/26/2009	74 FR 43043

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA)
RIN: 0910-AG11

View Related Documents

Title: Revision of the Requirements for Publication of License Revocation
Abstract: The Food and Drug Administration (FDA) is amending the biologics regulations to clarify the regulatory procedures for notifying the public about the revocation of a biologics license. We are taking this action as part of our continuing effort to eliminate or modify those regulations that are outdated or otherwise in need of reform without diminishing public health protection.

Priority: Info./Admin./Other
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 601.8 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 15 USC 1451 to 1561; 21 USC 321; 21 USC 351 to 353; 21 USC 355; 21 USC 356b; 21 USC 360; 21 USC 360c to 360f; 21 USC 360h to 360j; 21 USC 371; 21 USC 374; 21 USC 379e; 21 USC 381; 42 USC 216; 42 USC 241; 42 USC 262 and 263; 42 USC 264, sec 122; PL 105-115, 111 Stat. 2322 (21 USC 355 note)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Direct Final Rule	05/05/2009	74 FR 20583
NPRM-Companion to Direct Final Rule	05/05/2009	74 FR 20663
Confirmation of Effective Date	08/21/2009	74 FR 42175

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG19

View Related Documents

Title: Applications for Food and Drug Administration Approval to Market a New Drug; Postmarketing Reports; Reporting Information About Authorized Generic Drugs

Abstract: The Food and Drug Administration Amendments Act of 2007 (FDAAA) requires that FDA publish a list of all authorized generic drugs identified in an annual report since 1999, and that the agency update the list quarterly. FDA published a final rule in the Federal Register of July 29, 2009 (74 FR 37163), to, among other tings, require submission of a copy of the portion of annual reports containing the authorized generic information identified in FDAAA to a central office in FDA that compiles and updates the list, to permit easier identification of the information.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 314.3(b); 21 CFR 314.81(b)(2)(ii)(b) (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 355(t)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/29/2008	73 FR 56529
NPRM Comment Period End	12/15/2008	
Final Action	07/29/2009	74 FR 37163

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Federal
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Food and Drug Administration (FDA) RIN: 0910-AG21

View Related Documents

Title: Classification of Dental Amalgam, Reclassification of Dental Mercury, Designation of Special Controls for Dental Amalgam, Mercury, and Amalgam Alloy

Abstract: The Food and Drug Administration (FDA) is issuing a final rule classifying dental amalgam into class II, reclassifying dental mercury from class I to class II, and designating a special control to support the class II classifications of these two devices, as well as the current class II classification of amalgam alloy. The three devices are now classified in a single regulation. The special control for the devices is a guidance document entitled, “Class II Special Controls Guidance Document: Dental Amalgam, Mercury, and Amalgam Alloy.” This action is being taken to establish sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of these devices.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 21 CFR 872 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 351; 21 USC 360; 21 USC 360c; 21 USC 360e; 21 USC 360j; 21 USC 371
Legal Deadline:

Action	Source	Description	Date
Other	Judicial	settlement agreement to complete the classification process for encapsulated amalgam alloy and dental mercury.	07/28/2009

Timetable:

Action	Date	FR Cite
Final Action	08/04/2009	74 FR 38686

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC)
RIN: 0920-AA16

View Related Documents

Title: Amendments to Powered Air-Purifying Respirator Requirements for Approval of Respiratory Protection Devices
Abstract: NIOSH plans to modify sections of 42 CFR part 84 concerning performance testing and other specifications for the certification of powered air-purifying respirators. These respirators are used in a variety of workplace applications, including emergency response activities.

Priority: Other Significant
Agenda Stage of Rulemaking: PreRule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: 42 CFR 84 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 28 USC 651; 30 USC 3; 30 USC 7; 30 USC 11; 30 USC 842; 30 USC 844
Legal Deadline: None

Timetable:

Action	Date	FR Cite
ANPRM	06/00/2010	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Federalism: Undetermined
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA14

View Related Documents

Title: Foreign Quarantine Regulations, Proposed Revision of HHS/CDC Animal Importation Regulations

Abstract: By statute, the Secretary of Health and Human Services has broad authority to prevent introduction, transmission, and spread of communicable diseases from foreign countries into the United States and from one State or possession into another. The Secretary has designated the authority to prevent the introduction of diseases from foreign countries to the Director, Centers for Disease Control and Prevention (CDC). CDC also enforces entry requirements for certain animals, etiologic agents and vectors deemed to be of public health significance. Currently the regulations restrict the importation of nonhuman primates, dogs, cats, small turtles, etiologic agents, hosts and vectors, such as bats (42 CFR sections 71.53, 71.51, 71.52, 71.54). In addition, CDC has recently issued a series of emergency orders, restricting the importation of African rodents (42 CFR section 71.56) and civets (67 FR 3364-01). CDC is issuing this Notice of Proposed Rulemaking (NPRM) to revise the regulations for importation of certain animals and vectors into the United States (42 CFR parts 71, Subpart F).

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 71 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 264
Legal Deadline: None

Timetable:

Action	Date	FR Cite
ANPRM	07/31/2007	72 FR 41676
ANPRM Comment Period End	10/01/2007	
Notice Extending ANPRM Comment Period	10/01/2007	72 FR 55729
ANPRM Extended Comment Period End	12/01/2007	
NPRM	06/00/2010	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Undetermined
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA21

View Related Documents

Title: Amendments to Specifications for Medical Examinations of Underground Coal Miners

Abstract: NIOSH plans to modify sections of 42 CFR part 37 to allow for the use of digital radiography in medical screening of coal miners for coal workers' pneumoconiosis. Current provisions of these regulations require the use of film radiography

which is being phased out of use at medical facilities in the United States.

Priority: Info./Admin./Other
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 42 CFR 37 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 30 USC 843
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	06/00/2010	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC)
RIN: 0920-AA23

View Related Documents

Title: Control of Communicable Diseases: Foreign Quarantine Regulations, Proposed Revision of HHS/CDC Nonhuman Primate Regulations

Abstract: By statute, the Secretary of Health and Human Services has broad authority to prevent introduction, transmission, and spread of communicable diseases from foreign countries into the United States and from one State or possession into another. The Secretary has delegated the authority to prevent the introduction of diseases from foreign countries to the Director, CDC. CDC also enforces entry requirements for certain animals, etiologic agents, and vectors deemed to be of public health significance. CDC is proposing to amend its regulations related to the importation of live nonhuman primates (NHPs) by extending existing requirements for the importation of cynomolgus, African green, and rhesus monkeys to all NHPs. The agency also is proposing to reduce the frequency at which importers of the three species are required to renew their registrations, (from every 180 days to every two years). CDC proposes to incorporate existing guidelines into the regulations and add new provisions to address NHPs imported as part of a circus or trained animal act, NHPs imported by zoological societies, the transfer of NHPs from approved laboratories, and non-live imported NHP products. CDC is also proposing that all NHPs be imported only through ports of entry where a CDC quarantine station is located.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 71.53 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 264
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/00/2010	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Undetermined
Federalism: Undetermined
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA28

View Related Documents

Title: Medical Examination of Aliens

Abstract: CDC is amending its regulations that govern medical examinations that aliens must undergo before they may be admitted to the United States. Specifically, HHS/CDC is amending its regulations to update vaccination requirements, definitional changes for drug abuse and drug addition, scope of medical examination from the list of "communicable diseases of public health significance." We are taking this action to afford CDC the maximum flexibility it needs to identify and respond to newly emerging and re-emerging diseases. These changes are needed to improve the U.S. Government's ability to prevent the importation of infectious diseases that are currently causing severe illness and death in regions of the world where large numbers of U.S.-bound immigrants and refugees reside These changes will reduce the health-security threat to the United States from emerging diseases without imposing an undue burden on either the aliens or the health-care system in U.S. resettlement communities.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: 42 CFR 34 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 8 USC 1182; 8 USC 1222; 42 USC 252
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	05/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Undetermined
Small Entities Affected: No
Federalism: Undetermined
Energy Affected: Yes
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA30

View Related Documents

Title: Possessions, Use, and Transfer of Select Agents and Toxins--Pandemic Influenza

Abstract: The biological agents and toxins listed in section 73.3 of title 42 of the Code of Federal Regulations have been determined by the Secretary of the U.S. Department of Health and Human Services (HHS) to have the potential to pose a severe threat to public health and safety. On October 20, 2005, we published in the Federal Register an interim final rule adding the reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments to the list of HHS select agents and toxins. Based on public comments we received, we are proposing to revise the entry for the 1918 pandemic influenza virus from "reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments" to "Chimeric influenza viruses containing gene segments from the 1918 pandemic influenza strain."

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 42 CFR 73.3 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 107-188
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Energy Affected: No
Related RINs: Related to 0920-AA09
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC)
RIN: 0920-AA33

View Related Documents

Title: Total Inward Leakage Requirements for Respirators;
Abstract: The Centers for Disease Control and Prevention (CDC) proposes to establish total inward leakage (TIL) requirements under 42 CFR part 84 for half-mask air-purifying particulate respirators approved by the National Institute for Occupational Safety and Health (NIOSH) of CDC.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 84 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 29 USC 651 et seq; 29 USC 657(g); 30 USC 3; 30 USC 7; 30 USC 811; 30 USC 842(h) and 844
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	10/30/2009	74 FR 56141
NPRM Comment Period End	12/29/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC)
RIN: 0920-AA04

View Related Documents

Title: Amendments to Quality Assurance and Administrative Provision for Approval of Respiratory Protective Devices

Abstract: NIOSH plans to modify the Administrative/Quality Assurance sections of 42 CFR part 84, Approval of Respiratory Protective Devices. Areas for potential modification in this module are: 1) Upgrade of quality assurance requirements; 2) ability to use private sector quality auditors and private sector testing laboratories in the approval program; and 3) revised approval label requirements.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 84 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 29 USC 651 et seq; 30 USC 3; 30 USC 5; 30 USC 7; 30 USC 811; 30 USC 842(h); 30 USC 844
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/10/2008	73 FR 75045
NPRM Comment Period End	02/09/2009	
NPRM Comment Period End	03/04/2009	74 FR 9381
NPRM Comment Period Reopened	04/10/2009	
NPRM Comment Period Reopened	05/21/2009	74 FR 23815
NPRM Comment Period End	10/09/2009	
Final Action	01/00/2010	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA10

View Related Documents

Title: Amendments to Self-Contained Breathing Apparatus Requirements for Approval of Respiratory Protective Devices

Abstract: NIOSH plans to modify sections of 42 CFR part 84 concerning performance testing and other specifications for the certification of closed-circuit, self-contained breathing apparatus. These respiratory protective devices are used in emergencies for the protection of miners and workers in other industries.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 84 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 29 USC 651 et seq; 30 USC 3; 30 USC 5; 30 USC 7; 30 USC 811; 30 USC 842; 30 USC 844
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/10/2008	73 FR 75027
NPRM Comment Period End	02/09/2009	
NPRM Comment Period Reopened	03/04/2009	74 FR 9380
NPRM Comment Period End	04/10/2009	

NPRM Comment Period Reopened	05/21/2009	74 FR 23814
NPRM Comment Period End	06/19/2009	
Final Action	01/00/2010	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA12

View Related Documents

Title: Control of Communicable Diseases Foreign Quarantine

Abstract: By statute, the Secretary of Health and Human Services has broad authority to prevent introduction, transmission, and spread of communicable diseases from foreign countries into the United States and from one State or possession into another. Quarantine regulations are divided into two parts: Part 71 dealing with foreign arrivals and part 70 dealing with interstate matters. This rule (42 CFR part 71) will update and improve CDC's response to both global and domestic disease threats by creating a multi-tiered illness detection and response process thus substantially enhancing the public health system's ability to slow the introduction, transmission, and spread of communicable disease. The rule will also modify current Federal regulations governing the apprehension, quarantine isolation and conditional release of individuals suspected of carrying a quarantinable disease while respecting individual autonomy. CDC maintains quarantine stations at 20 ports of entry staffed with medical and public health officers who respond to reports of diseases from carriers. According to the statutory scheme, the President determines through Executive Order which diseases may subject individuals to quarantine. The current disease list, which was last updated in April 2005, includes cholera, diphtheria, tuberculosis, plague, smallpox, yellow fever, viral hemorrhagic fevers, severe acute respiratory syndrome (SARS), and influenza caused by novel or reemergent influenza viruses that are causing, or have the potential to cause a pandemic.

Priority: Economically Significant
Agenda Stage of Rulemaking: Final Rule
Major: Yes
Unfunded Mandates: Private Sector
CFR Citation: 42 CFR 71 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 243; 42 USC 248 and 249
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	11/30/2005	70 FR 71892
NPRM Comment Period End	01/20/2006	
Final Action	03/00/2010	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA22

View Related Documents

Title: Control of Communicable Diseases: Interstate Quarantine

Abstract: By statute, the Secretary of Health and Human Services has broad authority to prevent introduction, transmission, and spread of communicable diseases from foreign countries into the United States and from one State or possession into another. Quarantine regulations are divided into two parts: Part 71 dealing with foreign arrivals and part 70 dealing with interstate matters. This rule (42 CFR part 70) will update and improve CDC's response to both global and domestic disease threats by creating a multi-tiered illness detection and response process thus substantially enhancing the public health system's ability to slow the introduction, transmission, and spread of communicable disease. The rule will also modify current Federal regulations governing the apprehension, quarantine, isolation and conditional release of individuals suspected of carrying a quarantine disease, while respecting individual autonomy. Entities affected by the rule are those that are directly involved in the movement of persons, animals, and articles in interstate traffic. CDC maintains quarantine stations at 20 ports of entry staffed with medical and public health officers who respond to reports of diseases from carriers. According to the statutory scheme, the President determines through Executive Order which diseases may subject individuals to quarantine or isolation. The current disease list, which was last updated in April 2005, includes cholera, diphtheria, tuberculosis, plague, smallpox, yellow fever, viral hemorrhagic fevers, severe acute respiratory syndrome (SARS), and influenza caused by novel or re-emergent influenza viruses that are causing, or have the potential to cause, a pandemic.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: Undetermined
Unfunded Mandates: Private Sector
CFR Citation: 42 CFR 70 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 28 USC 198; 28 USC 231; 25 USC 1661; 42 USC 243; 42 USC 248 and 249; 42 USC 264; 42 USC 266 to 268; 42 USC 270 to 272; 42 USC 2001
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	11/30/2005	70 FR 71892
NPRM Comment Period End	01/30/2006	
Final Action	03/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Undetermined
Small Entities Affected: Business
Federalism: Undetermined
Energy Affected: Undetermined
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA25

View Related Documents

Title: Possession, Use, and Transfer of Select Agents and Toxins--Biennial Review

Abstract: The Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Subtitle A of Public Law 107-188 (42 U.S.C. 262a), requires the HHS Secretary to establish by regulation a list of each biological agent and each toxin that has the potential to pose a severe threat to public health and safety. In determining whether to include an agent or toxin on the list, the HHS Secretary considers the effect on human health of exposure to an agent or toxin; the degree of contagiousness of the agent and the methods by which the agent or toxin is transferred to humans; the availability and

effectiveness of pharmacotherapies and immunizations to treat and prevent illnesses resulting from an agent or toxin; the potential for an agent or toxin to be used as a biological weapon; and the needs of children and other vulnerable populations. The Bioterrorism Preparedness Act requires that the HHS Secretary review and republish the list of select agents and toxins on at least a biennial basis. This document completes the biennial review and republication of the lists of biological agents and toxins regulated by the U.S. Department of Health and Human Services. To assist with the biennial review, HHS reviewed recommendations provided by subject matter experts and the Intragovernmental Select Agents and Toxins Advisory Committee.

Priority: Economically Significant
Agenda Stage of Rulemaking: Final Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 42 CFR 73.3 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 107-188
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	08/28/2007	72 FR 166
NPRM Comment Period End	10/29/2007	
Final Action	12/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC)
RIN: 0920-AA27

View Related Documents

Title: Control of Communicable Diseases: Interstate Quarantine, Passenger Information

Abstract: By statute, the Secretary of Health and Human Services has broad authority to prevent introduction, transmission, and spread of communicable diseases from one State or possession into another. Quarantine regulations are divided into two parts: Part 71 dealing with foreign arrivals and part 70 dealing with interstate matters. The CDC Director has been delegated the responsibility for carrying out these regulations. The Director's authority to investigate suspected cases and potential spread of communicable disease among interstate travelers is thus not limited to those known or suspected of having a quarantinable disease, but rather all communicable diseases that may necessitate a public health response. Among the fundamental components of the public health response to the report of a person with a communicable disease is the identification and evaluation of individuals who may have been exposed. This provision, which was proposed section 70.4, would require any airline operating in interstate traffic to solicit and electronically submit certain passenger information to CDC for use in contact tracing when necessary to protect the vital interests of an individual, or other persons, in regard to significant health risks.

Priority: Economically Significant
Agenda Stage of Rulemaking: Final Rule
Major: Yes
Unfunded Mandates: Private Sector
CFR Citation: 42 CFR 70 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 25 USC 198.231; 25 USC 1661; 42 USC 243; 42 USC 248; 42 USC 249; 42 USC 264; 42 USC 266 to 268; 42 USC 270 to 272; 42 USC 2001
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	11/30/2005	70 FR 71892
NPRM Comment Period End	01/30/2006	
Final Action	03/00/2010	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: No
Federalism: No
Energy Affected: Undetermined
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA17

View Related Documents

Title: Amendments to Performance Requirements for Chemical, Biological, Radiological, and Nuclear (CBRN) Approval of Respiratory Protective Devices

Abstract: NIOSH plans to modify sections of 42 CFR part 84 concerning performance testing and other specifications for the certification of closed-circuit, self-contained breathing apparatus; supplied air respirators; and combination (supplied air and air purifying capable) respirators against CBRN respiratory hazards. These respirators are used in emergency response situations.

Priority: Other Significant Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined Unfunded Mandates: No
CFR Citation: 42 CFR 84 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 29 USC 651; 30 USC 3; 30 USC 5; 30 USC 7; 30 USC 11; 30 USC 842l; 30 USC 844
Legal Deadline: None

Timetable:

Action	Date	FR Cite
ANPRM	12/00/2010	

Regulatory Flexibility Analysis Required: Undetermined Government Levels Affected: No
Small Entities Affected: Business Federalism: Undetermined
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC) RIN: 0920-AA31

View Related Documents

Title: Possession, Use, and Transfer of Select Agents and Toxins (Sars-CoV)

Abstract: The biological agents and toxins listed in section 73.3 of title 42 of the Code of Federal Regulations have been determined by the Secretary of the U.S. Department of Health and Human Services (HHS) to have the potential to pose a severe threat to public health and safety. We are also proposing to add SARS-associated coronavirus (SARS-CoV) of HHS select agents and toxins. We are proposing this action because SARS-CoV (1) causes significant mortality, especially in the elderly; (2) has the capability of easily to transmit from human to human; (3) there is currently no method to treat or prevent infections caused by the SARS-CoV virus; and (4) it has been documented that the virus persists in the environment.

Priority: Economically Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 42 CFR 73.3 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 107-188
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM	07/13/2009	74 FR 132
NPRM Comment Period End	09/11/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC)
RIN: 0920-AA32

View Related Documents

Title: Possession, Use and Transfer of Select Agents and Toxins

Abstract: The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 authorizes the HHS Secretary to regulate the possession, use, and transfer of select agents and toxins that have the potential to pose a severe threat to public health and safety. These regulations are set forth at 42 CFR 73. Criteria used to determine whether a select agent or toxin should be included under the provisions of these regulations are based on: 1) the effect on human health as a reuslt of exposure to the agent or toxin, 2) the degree of contagiousness of the agent or toxin, 3) the methods by which the agent or toxin is transferred to humans, 4) the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent andy illness resulting from infection by the agent or toxin, and 5) any other criteria, including the needs of children and other vulnerable populations that the HHS Secretary considers appropriate. Based on these criteria, we are proposing to amend the list of HHS select agents and toxins by adding Chapare virus to the list. After consulting with subject matter experts from CDC, the National Institutes of Health (NIH), the Food Drug Administration (FDA), the United States Department of Agriculture (USDA) /Animal and Plant Health Inspection Service (APHIS), USDA/Agricultural Research Service (ARS), USDA/CVB (Center for Veterinary Biologics), and the Department of Defense (DOD)/United States Army Medical Research Institute for Infectious Diseases (USAMRIID) and review of relevant published studies, we believe the Chapare virus should be added to the list of HHS select agents and toxins based on our conclusion that the Chapare virus has been phylogenetically identified as a Clade B arenavirus and is closely related to other South American arenaviruses that cause haemorrhagic fever, particularly Sabia virus.

Priority: Economically Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 42 CFR 73.3 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 107-188
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM	08/19/2009	74 FR 159
NPRM Comment Period End	10/19/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC)
RIN: 0920-AA24

View Related Documents

Title: Possession, Use, and Transfer of Select Agents and Toxins

Abstract: The biological agents and toxins listed in section 73.3 of title 42 of the Code of Federal Regulations have been determined by the Secretary of the U.S. Department of Health and Human Services (HHS) to have the potential to pose a severe threat to public health and safety. On October 20, 2005, we published in the Federal Register an interim final rule adding the reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments to the list of HHS select agents and toxins. Based on public comments we received, we are proposing to revise the entry for the 1918 pandemic influenza virus from “reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments” to “Chimeric influenza viruses containing gene segments from the 1918 pandemic influenza strain.” We are also proposing to add SARS-associated coronavirus (SARS-CoV) to the list of HHS select agents and toxins. We are proposing this action because SARS-CoV (1) causes significant mortality, especially in the elderly; (2) has the capability of easily being transmitted from human to human; (3) there is currently no method to treat or prevent infections caused by the SARS-CoV virus; and (4) it has been documented that the virus may persist in the environment.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 42 CFR 73.3 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 107-188
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Duplicate of 0920-AA30	11/17/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
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Department of Health and Human Services (HHS)
Centers for Disease Control and Prevention (CDC)
RIN: 0920-AA26

View Related Documents

Title: Medical Examination of Aliens: Removal of HIV Infection as a Communicable Disease of Public Health Significance

Abstract: Under the authority of section 212(a)(1)(A) of the Immigration and Nationality Act (INA) and section 325 of the Public Health Service Act, the Secretary of Health and Human Services promulgates regulations outlining the requirements for the medical examination of aliens and a list of any “communicable disease of public health significance” that make aliens ineligible for entry into the United States. HIV is currently included in this list of communicable diseases as defined in 42 CFR

part 34: Medical Examination of Aliens. CDC is proposing to remove HIV as a “communicable disease of public health significance” in 42 CFR part 34.2(b). This action aligns with an amendment in the United States Global Leadership Against HIV/AIDS, Tuberculosis and Malaria Reauthorization Act of 2008, signed on July 30, 2008, that removed language in the Immigration and Nationality Act that explicitly prohibited HIV-positive non-citizens from entering the United States without a visa waiver.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 34 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 252; 8 USC 1182; 8 USC 1222
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	07/02/2009	74 FR 31798
NPRM Comment Period End	08/17/2009	
Final Action	11/02/2009	74 FR 56547
Final Action Effective	01/04/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
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Department of Health and Human Services (HHS)
National Institutes of Health (NIH)
RIN: 0925-AA43

View Related Documents

Title: National Institutes of Health Loan Repayment Programs
Abstract: NIH proposes to issue a single set of regulations to govern all of its loan repayment (LRP) authorities. This action will include rescinding the current regulations at 42 CFR part 68a and at 42 CFR part 68c replaced by the new consolidated set of LRP regulations. This action will also include withdrawing the previously announced planned actions concerning NIH LRP authorities.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 68 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 216; 42 USC 288-5a; 42 USC 287c-33; 42 USC 288-1; 42 USC 288-3; 42 USC 288-5 and 288-6
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
National Institutes of Health (NIH) RIN: 0925-AA47

View Related Documents

Title: Endowment Program

Abstract: The Director of the National Center for Minority Health and Health Disparities Research is authorized under section 485E(h)(1) of the Public Health Service Act to carry out a program to facilitate minority health disparities research and other health disparities research by providing for research endowments at centers of excellence under section 736 (Public Health Service Act). NIH plans to issue implementing regulations to govern these research endowments.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 52i (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 216; 42 USC 287c-31
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
National Institutes of Health (NIH) RIN: 0925-AA48

View Related Documents

Title: Undergraduate Scholarship Program Regarding Professions Needed by the National Institutes of Health

Abstract: Section 487D of the Public Health Service Act, as added by NIH Revitalization Act of 1993, creates a program offering scholarships to individuals from disadvantaged backgrounds who are enrolled as full-time students at accredited institutions pursuing academic programs appropriate for careers in professions needed by NIH. For each year of scholarship support, the recipient agrees to provide service (employment) after graduation, at NIH, for 1 year. Additionally, the individual agrees to provide at least 10 consecutive weeks of service (employment) at NIH during which the individual is attending the educational institution and receiving the NIH scholarship. The proposed new regulations will govern this program.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No

CFR Citation: 42 CFR 68b (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 216; 42 USC 288-4
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/00/2010	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
National Institutes of Health (NIH) RIN: 0925-AA49

View Related Documents

Title: NIH Training Grants

Abstract: NIH plans to amend the Agency's existing training grants regulations to: (1) Reflect their applicability to the training authorities set forth in sections 464W and 485F of the Public Health Service Act; (2) reflect their applicability to training programs of the National Center on Minority Health and Health Disparities (NCMHD) and Fogarty International Center (FIC) awards; and (3) reflect their applicability for grants that the National Institute of Nursing Research (NINR) makes to nonprofit institutions to provide training and instruction in the study and investigation of the prevention of disease, health promotion, and the nursing care of individuals with and the families of individuals with acute and chronic illnesses.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 63a (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 216; 42 USC 2421; 42 USC 285q-1; 42 USC 287c-31 and 287c-32
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/00/2010	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
National Institutes of Health (NIH) RIN: 0925-AA53

View Related Documents

Title: Amendment of Regulation of the Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought and Responsible Prospective Contractors; Request for Comments

Abstract: On behalf of the Department of Health and Human Services (HHS) and the Public Health Service (PHS), a component of DHHS, the National Institutes of Health (NIH), proposes to issue an Advanced Notice of Proposed Rulemaking (ANPRM) to seek comments from the public on whether DHHS should amend the regulations on the Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service Funding Is Sought (42 CFR part 50 subpart F) and Responsible Prospective Contractors (45 CFR part 94). The existing regulations provide standards to ensure that there is no reasonable expectation that the design, conduct, and reporting of PHS-funded research will be biased by a conflicting financial interest of an investigator. Since the regulations' publication in 1995, biomedical research has progressively become more complex, the Federal Government, PHS-funded institutions and researchers, and the private sector have increasingly interacted in an effort to meet common public health goals, and recent public scrutiny has raised the question of whether a more rigorous approach to investigator disclosure, management of conflicts, and Federal oversight is required.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 94 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 216; 42 USC 289b-1; 42 USC 299c-4
Legal Deadline: None

Timetable:

Action	Date	FR Cite
ANPRM	05/08/2009	74 FR 21610
ANPRM Comment Period End	07/07/2009	
NPRM	12/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
National Institutes of Health (NIH) RIN: 0925-AA55

View Related Documents

Title: Expanded Registration and Results Reporting at ClinicalTrials.gov

Abstract: The National Institutes of Health (NIH) proposes to issue new regulations that will prescribe procedures for registering and reporting the results, including adverse events, of clinical trials in ClinicalTrials.gov, in accordance with section 801 of the Food and Drug Administration Amendments Act of 2007, (FDAAA, Pub. L. 110-85). Rather than proceed with separate regulations for registration and results reporting as previously announced, the agency intends to proceed with a single rulemaking to implement the expanded registry, results reporting, and adverse event information reporting requirements of the statute. The rulemaking will also consider topics that the statue requires to be addressed in regulations intended to provide more complete results information and to enhance patient access to and understanding of the results of clinical trials [as

codified in 42 U.S.C. 282(j)(3)(D), including whether results information should be required to be submitted for applicable clinical trials of drugs, biological products, or devices that have not been approved, licensed, or cleared by the Food and Drug Administration, and whether narrative summaries of clinical trials and their results can be included in the data bank without being misleading or promotional. These topics were the subject of discussion at the Public Meeting organized by the agency in April 2009, and of written public comments. The regulations will identify the trials that are subject to the registration and results reporting requirements (including adverse event reporting); the specific information and format of the information that must be submitted to ClinicalTrials.gov; deadlines for registering and reporting results; procedures for extending the deadlines or wavering the submission requirements; and procedures for agency review and public posting of submitted information.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 3 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 216, 282(j)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		09/27/2010

Timetable:

Action	Date	FR Cite
NPRM	02/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
National Institutes of Health (NIH)
RIN: 0925-AA57

View Related Documents

Title: National Institutes of Health Construction Grants

Abstract: The National Institutes of Health (NIH) proposes to review and/or amend the existing regulations at 42 CFR 52b governing grants awarded by the agency and its components for construction of new buildings and the alteration, renovation, remodeling, improvement, expansion, and repair of existing buildings, including the provision of equipment necessary to make the building (or applicable part of the building) suitable for which it was constructed to update the regulations. The NIH proposes to revise and/or amend the regulations to promote consistency with the Department of Health and Human Services (HHS) regulations at 45 CFR 74 applicable to recovery and insurance coverage. Specifically, NIH proposes to replace language in section 52b.9(a)(1) with the language in 45 CFR 74.32(c)(2), and replace the language in section 52b.10(n) with the language in 45 CFR 74.31. The narrative in section 52b.12(b) that refers to the National Cancer Institute having copies of certain resource documents would be updated. Citations in section 52b.12(c) Design and construction standards would be updated. Section 52b.14(c) would be amended to reference Executive Order 12372, Intergovernmental Review of Federal Programs. Reference numbers (1), (3), (4), (5), (6) and (7) in section 53b.14(d) Policies would be updated.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 42 CFR 52b (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 216; 42 USC 285a-2; 42 USC 285a-3; 42 USC 285b-3; 42 USC 285b-4; 42 USC 285d-6; 42 USC 285i; 42 USC 285m-3; 42 USC 285o-4; 42 USC 287a-2; 42 USC 287a-3; 42 USC 300cc-41

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/00/2010	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
National Institutes of Health (NIH) RIN: 0925-AA42

View Related Documents

Title: Grants for Research Projects

Abstract: NIH proposes to amend the regulations governing grants for research projects by revising the definition of Principal Investigator to mean one or more individuals designated by the grantee in the grant application and approved by the Secretary, who is or are responsible for the scientific and technical direction of the project, rather than limiting the role of principal investigator to one single individual when that more accurately reflects the management needs of a research project.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 52 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 216
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	06/25/2007	72 FR 34655
NPRM Comment Period End	08/24/2007	
Final Action	12/00/2009	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
National Institutes of Health (NIH) RIN: 0925-AA52

View Related Documents

Title: Procedures for Registration of Applicable Clinical Trials in the ClinicalTrials.gov Registry

Abstract: NIH plans to issue new regulations that will prescribe specific procedures for registering clinical trails in the expanded ClinicalTrials.gov registry, and define the information that must be provided. Required information will include descriptive information, recruitment information, location and contact information, and administrative information. The regulations will define additional information needed to comply with specific statutory requirements related to search capabilities, enforcement, posting of information related to trials of uncleared/unapproved devices, as well as to support efficient entry of valid data, link the trials in the registry database to their results, and to provide a comprehensive registry of clinical trials for the public.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 282(i)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Withdrawn	08/26/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business; Organizations
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
National Institutes of Health (NIH) RIN: 0925-AA54

View Related Documents

Title: Reporting Results of Applicable Clinical Trials in the Clinical Trials.gov Data Bank

Abstract: The National Institutes of Health plans to issue new regulations that will prescribe specific procedures for reporting results information to the expanded ClinicalTrials.gov data bank and will define the information that must be provided to meet the requirements established in the Food and Drug Administration Amendments Act of 2007 (Public Law 110-85). The regulations will include deadlines for reporting results informastion, procedures for requesting extensions and waivers for delaying submission, and the format for submitting results information.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 216; 42 USC 282(j)
Legal Deadline: None

Timetable:

Action	Date	FR Cite

Withdrawn	08/26/2009	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: Business
Energy Affected: Undetermined
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Government Levels Affected: No
Federalism: No

Department of Health and Human Services (HHS)
National Institutes of Health (NIH) RIN: 0925-AA56

View Related Documents

Title: Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought and Responsible Prospective Contractors

Abstract: On behalf of the Department of Health and Human Services (HHS) and the Public Health Service (PHS), a component of HHS, the National Institutes of Health (NIH), proposes to amend existing regulations on the Responsibility of Applicants for Promoting Objectivity in Research for which PHS Funding is Sought [42 CFR 50, subpart F] and Responsible Prospective Contractors [45 CFR 94]. The existing regulations provide standards to ensure that there is no reasonable expectation that the design, conduct, and reporting of PHS-funded research will be biased by a conflicting financial interest of an investigator. Since the regulations' publication in 1955, biomedical research has progressively become more complex; the Federal Government, PHS-funded institutions and researchers, and the private sector have increasingly interacted in an effort to meet common public health goals, leading to a need to determine if there are needs to enhance the requirements for investigator disclosure, management of conflicts, and Federal oversight.

Priority: Substantive, Nonsignificant
Major: No
Agenda Stage of Rulemaking: Completed Action
Unfunded Mandates: No
CFR Citation: 42 CFR 50, subpart F; 45 CFR 94 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 216; 42 USC 289B-1; 42 USC 299C-3
Legal Deadline: None

Timetable:

Action	Date	FR Cite
ANPRM	05/08/2009	74 FR 21610
ANPRM Comment Period End	07/07/2009	
Withdrawn	11/17/2009	

Regulatory Flexibility Analysis Required: No
Federalism: No
Energy Affected: No
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Government Levels Affected: No

Department of Health and Human Services (HHS)
Substance Abuse and Mental Health Services Administration (SAMHSA) RIN: 0930-AA14

View Related Documents

Title: Opioid Drugs in Maintenance or Detoxification Treatment of Opiate Addition

Abstract: This rule will amend the Federal opioid treatment program regulations. It will modify the dispensing requirements for buprenorphine and buprenorphine combination products that are approved by the Food and Drug Administration (FDA) for opioid dependence and used in federally certified and registered opioid treatment programs.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 8 to 12 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 21 USC 823 (9); 42 USC 257a; 42 USC 290aa(d); 42 USC 290dd-2; 42 USC 300xx-23; 42 USC 300x-27(a); 42 USC 300y-11
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	06/19/2009	74 FR 29153
NPRM Comment Period End	08/18/2009	
Final Action	06/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Substance Abuse and Mental Health Services Administration (SAMHSA) RIN: 0930-AA10

View Related Documents

Title: Requirements Governing the Use of Seclusion and Restraint in Certain Nonmedical Community-Based Facilities for Children and Youth

Abstract: The Secretary is required by statute to publish regulations governing States that license nonmedical, community-based residential facilities for children and youth. The regulation requires States to develop licensing rules and monitoring requirements concerning behavior management practice that will ensure compliance; requires States to develop and implement such licensing rules and implementation requirements within one year; and ensures that States require such facilities to have adequate staff, and that the States provide training for professional staff.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 106-310, 42 USC 290jj to 290jj-2
Legal Deadline:

Action	Source	Description	Date
NPRM	Statutory		04/00/2001

Timetable:

Action	Date	FR Cite

NPRM	00/00/0000	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: State
Federalism: Yes
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP68

View Related Documents

Title: Implementing Regulations for Reauthorization of the Children's Health Insurance Program (CHIP) (CMS-2301-P)
Abstract: This proposed rule would reauthorize the Children's Health Insurance Program (CHIP) and introduce several new features as a result of the passage of the Children's Health Insurance Program Reauthorization Act of 2009.

Priority: Other Significant Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined Unfunded Mandates: Undetermined
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: CHIPRA of 2009 (PL 111-3)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/00/2010	

Regulatory Flexibility Analysis Required: Undetermined Government Levels Affected: State
Federalism: Undetermined
Energy Affected: Undetermined
Related RINs: Related to 0938-AP54
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP70

View Related Documents

Title: Extension of Transitional Medical Assistance Under the American Recovery and Reinvestment Act of 2009 (CMS-2475-P)
Abstract: This proposed rule would extend the Transitional Medical Assistance (TMA) program through December 31, 2010 as a result of the American Recovery and Reinvestment Act of 2009.

Priority: Other Significant Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined Unfunded Mandates: Undetermined
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: American Recovery and Reinvestment Act of 2009 (PL 111-5)

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	01/00/2010	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: State; Tribal

Federalism: Undetermined

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP71

View Related Documents

Title: Children's Health Insurance Program (CHIP) Child Enrollment Contingency Fund Payments (CMS-2488-P)

Abstract: This proposed rule would establish the "CHIP contingency fund" to eliminate State shortfalls in funding beginning in Fiscal Year 2009 as a result of the Children's Health Insurance Program Reauthorization Act of 2009.

Priority: Other Significant

Agenda Stage of Rulemaking: Proposed Rule

Major: Undetermined

Unfunded Mandates: Undetermined

CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: Children's Health Insurance Program Reauthorization Act of 2009 (PL 111-3)

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/00/2010	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: State

Federalism: Undetermined

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP77

View Related Documents

Title: Revisions to the Medicare Advantage and Medicare Prescription Drug Benefit Programs for Contract Year 2011 (CMS-

4085-F)

Abstract: This proposed rule sets forth programmatic and operational changes to the Medicare Advantage and Prescription Drug Benefit programs (for example, strengthens beneficiary protections and sponsor entrance and exit rules, provides plan offerings with meaningful differences, improves payment rules and data collection for oversight and quality assessment).

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Yes
Unfunded Mandates: Private Sector
CFR Citation: 42 CFR 417; 42 CFR 422 and 423; 42 CFR 480 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: MMA 2003; MIPPA (title XVIII of the Social Security Act)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	10/22/2009	74 FR 54634
NPRM Comment Period End	12/07/2009	
Final Action	10/00/2012	

Regulatory Flexibility Analysis Required: Organizations
Government Levels Affected: State
Federalism: No
Energy Affected: Undetermined

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AP78

View Related Documents

Title: Electronic Health Record (EHR) Incentive Program (CMS-0033-P)

Abstract: The Medicare and Medicaid Health IT provisions in the American Recovery and Reinvestment Act of 2009 promote the adoption and meaningful use of certified electronic health records (EHRs). The Recovery Act authorized incentive payments for eligible professionals (EPS) and hospitals participating in Medicare and Medicaid for becoming meaningful users of certified EHRs. The law established maximum annual incentive amounts and includes Medicare penalties for failing to meaningfully use EHRs beginning in 2015 for professionals and hospitals that fail to adopt certified EHRs.

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Yes
Unfunded Mandates: Undetermined
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-5 (The American Recovery and Reinvestment Act of 2009, Title IV of Division B, Medicare and Medicaid Health Information Technology)
Legal Deadline: Establishes policies and procedures required before the incentive program can begin. Additionally supplemental payments are available in 2011 and 2012. If eligible professionals and hospitals are not meaningful Electronic Health Record users by 2015 there will be a Medicare payment adjustment imposed

Action	Source	Description	Date
Other	Statutory	Date can start incentive payments to hospitals (Medicare)	10/01/2010
Other	Statutory	Date can start incentive payments to eligible professionals (Medicare)	01/01/2011

Regulatory Plan:

Statement of Need: This rule would implement provisions of the American Recovery and Reinvestment Act of 2009 (Recovery Act) that authorizes incentive payments to EPS and eligible hospitals participating in the Medicare and Medicaid programs for adopting and becoming meaningful users of certified EHR technology.

Legal Basis: Title IV of Division B of the Recovery Act includes provisions to promote the adoption of interoperable health information technology (HIT) to promote the meaningful use of health information technology to improve the quality and value of American health care. These provisions together with Title XIII of Division A of the Recovery Act may be cited as the "Health Information Technology for Economic and Clinical Health Act" or the "HITECH Act". CMS is charged with developing the incentive programs outlined in Division B, Title IV of the HITECH Act.

Alternatives: There are no alternatives; this is a statutory requirement.

Costs and Benefits: Under Medicare, payment adjustments will be made starting in 2015 if EPs and eligible hospitals are not meaningful users of certified EHR technology. The benefits of the adoption of HIT are difficult to quantify. There is the potential of reduced medical costs through efficiency improvements. Additionally, HIT could help prevent medical errors and adverse drug interactions.

Risks: If this rule is not published, CMS will be unable to pay incentives for the adoption and meaningful use of EHRs.

Timetable:

Action	Date	FR Cite
NPRM	12/00/2009	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: State

Federalism: Undetermined

Related RINs: Related to 0991-AB58

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP79

View Related Documents

Title: Revisions to Payment Policies Under the Physician Fee Schedule and Part B for CY 2011 (CMS-1503-P)

Abstract: This major proposed rule would revise payment polices under the physician fee schedule, as well, as other policy changes to payment under Part B for CY 2011. (The statute requires the proposed and subsequent final rule publish by 11/1/10.)

Priority: Economically Significant

Agenda Stage of Rulemaking: Proposed Rule

Major: Yes

Unfunded Mandates: Undetermined

CFR Citation: 42 CFR 405; 42 CFR 410 to 411; 42 CFR 413 to 414; 42 CFR 426 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: Social Security Act, sec 1102; Social Security Act, sec 1871

Legal Deadline:

Action	Source	Description	Date
Other	Statutory		11/01/2010

Regulatory Plan:

Statement of Need: The statute requires that we establish each year, by regulation, payment amounts for all physicians' services furnished in all fee schedule areas. This major proposed rule would make changes affecting Medicare Part B payment

to physicians and other Part B suppliers. The final rule has a statutory publication date of November 1, 2010, an implementation date of January 1, 2011.

Legal Basis: Section 1848 of the Social Security Act (the Act) establishes the payment for physician services provided under Medicare. Section 1848 of the Act imposes a deadline of no later than November 1 for publication of the final physician fee schedule rule.

Alternatives: None. This is a statutory requirement.

Costs and Benefits: Total expenditures will be adjusted for CY 2011.

Risks: If this regulation is not published timely, physician services will not be paid appropriately.

Timetable:

Action	Date	FR Cite
NPRM	06/00/2010	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Energy Affected: Undetermined

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP80

View Related Documents

Title: Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and FY 2011 Rates and to the Long-Term Care Hospital PPS and RY 2011 Rates (CMS-1498-P)

Abstract: Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and FY 2011 Rates and to the Long Term Care Hospital PPS and RY 2011 Rates

Priority: Economically Significant

Agenda Stage of Rulemaking: Proposed Rule

Major: Yes

Unfunded Mandates: Undetermined

CFR Citation: 42 CFR 412 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: Sec 1886(d) of the Social Security Act

Legal Deadline:

Action	Source	Description	Date
NPRM	Statutory		04/01/2010
Other	Statutory		08/01/2010

Regulatory Plan:

Statement of Need: CMS annually revises the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs to implement changes arising from our continuing experience with these systems. In addition, we describe the proposed changes to the amounts and factors used to determine the rates for Medicare hospital inpatient services for operating costs and capital-related costs. Also, CMS annually updates the payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs). The proposed rule solicits comments on the proposed IPPS and LTCH payment rates and new policies. CMS will issue a final rule containing the payment rates for the 2011 IPPS and LTCHs at least 60 days before October 1, 2010.

Legal Basis: The Social Security Act (the Act) sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. The Act requires the Secretary to pay for the capital-related costs of hospital inpatient and Long Term Care stays under a prospective payment system (PPS). Under these PPSs, Medicare payment for hospital inpatient and Long Term Care operating and capital-related costs is made at predetermined, specific rates for each hospital discharge. These changes would be applicable to services furnished on or after October 1, 2010.

Alternatives: None. This is a statutory requirement.

Costs and Benefits: Total expenditures will be adjusted for FY 2011.

Risks: If this regulation is not published timely, inpatient hospital and LTCH services will not be paid appropriately beginning October 1, 2010

Timetable:

Action	Date	FR Cite
NPRM	04/00/2010	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Federal

Federalism: Yes

Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP82

View Related Documents

Title: Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2011 (CMS-1504-P)

Abstract: This major proposed rule would revise the Medicare hospital outpatient prospective payment system to implement applicable statutory requirements and changes arising from our continuing experience with this system. In addition, the proposed rule describes proposed changes to the amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the prospective payment system. The rule also proposes changes to the Ambulatory Surgical Center Payment System list of services and rates. These changes would be applicable to services furnished on or after January 1 annually. (The proposed and subsequent final rule must publish by 11/1/10.)

Priority: Economically Significant Agenda Stage of Rulemaking: Proposed Rule

Major: Yes Unfunded Mandates: Undetermined

CFR Citation: 42 CFR 410 to 413; 42 CFR 416 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: Sec 1833 of the Social Security Act

Legal Deadline:

Action	Source	Description	Date
Other	Statutory		11/01/2010

Regulatory Plan:

Statement of Need: Medicare pays over 4,200 hospitals for outpatient department services under the hospital outpatient prospective payment system (OPPS). The OPPS is based on groups of clinically similar services called ambulatory payment classification groups (APCs). CMS annually revises the APC payment amounts based on claims data, proposes new payment polices, and updates the payments for inflation using the hospital operating market basket. The proposed rule solicits comments on the proposed OPPS payment rates and new policies. This rule does not impact payments to critical access hospitals as they

are not paid under the OPPS. Medicare pays roughly 5,000 Ambulatory Surgical Centers (ASCs) under the ASC payment system. CMS annually revises the payment under the ASC payment system, proposes new policies, and updates payments for inflation using the Consumer Price Index for All Urban Consumers (CPI-U). CMS will issue a final rule containing the payment rates for the 2011 OPPS and ASC payment system at least 60 days before January 1, 2011.

Legal Basis: Section 1833 of the Social Security Act establishes Medicare payment for hospital outpatient services. The final rule revises the Medicare hospital OPPS to implement applicable statutory requirements and changes arising from our continuing experience with this system. In addition, the proposed and final rules describe changes to the outpatient APC system, relative payment weights, outlier adjustments, and other amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the prospective payment system as well as changes to the rates and services paid under the ASC payment system. These changes would be applicable to services furnished on or after January 1, 2011.

Alternatives: None. This is a statutory requirement.

Costs and Benefits: Total expenditures will be adjusted for CY 2011.

Risks: If this regulation is not published timely, outpatient hospital and ASC services will not be paid appropriately beginning January 1, 2011.

Timetable:

Action	Date	FR Cite
NPRM	06/00/2010	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Federal
Federalism: Undetermined
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AP84

View Related Documents

Title: Hospice Wage Index for FY 2011 (CMS-1523-P)

Abstract: This proposed rule would update the hospice wage index for fiscal year 2011. The wage index is used to reflect local differences in wage levels. These changes would be applicable to services furnished on or after October 1st annually.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: 42 CFR 418 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 1814(i)(1) of the Act; 1814(i) (2)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		08/00/2010

Timetable:

Action	Date	FR Cite
NPRM	04/00/2010	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined

Small Entities Affected: Business
Energy Affected: Undetermined
Federalism: Undetermined

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP87

View Related Documents

Title: Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2011 (CMS-1338-P)

Abstract: This proposed rule would update the payment rates used under the SNF PPS. These changes would be applicable to services furnished on or after October 1st annually.

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Yes
Unfunded Mandates: Undetermined
CFR Citation: 42 CFR 483 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Social Secrity Act, sec 1888(e)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		07/31/2010

Timetable:

Action	Date	FR Cite
NPRM	04/00/2010	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP88

View Related Documents

Title: Home Health Prospective Payment System Refinements and Rate Update for CY 2011 (CMS-1510-P)

Abstract: This proposed rule would update the 60-day national episode rate and the national per-visit rate amounts under the Medicare Prospective Payment System for home health agencies. These changes would be applicable to services furnished on or after January 1st annually.

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Yes
Unfunded Mandates: Undetermined
CFR Citation: 42 CFR 484 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Social Security Act, secs 1102 and 1871; 42 USC 1302 and 42 USC 1395(hh); Social Security Act, sec 1895
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		11/01/2010

Timetable:

Action	Date	FR Cite
NPRM	07/00/2010	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: Undetermined
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AP89

View Related Documents

Title: Prospective Payment System for Inpatient Rehabilitation Facilities for FY 2011 (CMS-1344-P)
Abstract: This proposed rule would update rates for the prospective payment system for inpatient rehabilitation facilities. These changes would be applicable to services furnished on or after October 1st annually.

Priority: Economically Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: Yes
Unfunded Mandates: Undetermined
CFR Citation: 42 CFR 412 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Social Security Act, sec 1886(j); PL 106-554; PL 106-113
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		08/01/2010

Timetable:

Action	Date	FR Cite
NPRM	04/00/2010	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AM73

View Related Documents

Title: Revisions to the Appeals Process for Initial Claim Determinations (CMS-4064-F)

Abstract: This final rule revises the Medicare appeals process by adding five levels of review. It will remove the distinction between the processing of initial determinations and appeals under part A and part B required by the Benefits Improvement and Protection Act of 2000 (BIPA).

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 401 and 405 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 1869 (b) of the Act, as amended by sec 521 of BIPA
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	MMA sec 902.	03/08/2010

Timetable:

Action	Date	FR Cite
Interim Final Rule	03/08/2005	70 FR 11419
Interim Final Rule Effective	05/01/2005	
Second Interim Final Rule	06/30/2005	70 FR 37700
Second Interim Final Rule Effective	07/01/2005	
Third Interim Final Rule	08/26/2005	70 FR 50214
Third Interim Final Rule Effective	09/26/2005	
Notice	02/29/2008	73 FR 11043
Second Notice	02/27/2009	74 FR 8867
Final Action	03/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Federal
Small Entities Affected: No
Federalism: No
Energy Affected: No
Related RINs: Related to 0938-AK69
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO82

View Related Documents

Title: Waiver of Disapproval of Nurse Aide Training Program in Certain Cases and Nurse Aide Petition for Removal of Information for Singular Finding of Neglect (CMS-2266-F)

Abstract: This rule permits a waiver of a nurse aide training disapproval as it applies to skilled nursing facilities, in the Medicare program, and nursing facilities, in the Medicaid program, that are assessed a civil money penalty of at least $5,000

for noncompliance that is not related to quality of care. This is a statutory provision enacted by section 932 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. This rule also codifies statutory provisions at sections 1819(g)(1)(D) and 1919(g)(1)(D) of the Social Security Act that permit the State to establish a procedure for a nurse aide to petition the State to have a singular finding of neglect removed from the nurse aide registry.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 483 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 932 (c) (2) MMA; secs 1819(g)(1)(D) and 1919(g)(1)(D) of the Social Security Act
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	MMA Section 902	11/23/2010

Timetable:

Action	Date	FR Cite
NPRM	11/23/2007	72 FR 65692
NPRM Comment Period End	12/24/2007	
Final Action	11/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AP40

View Related Documents

Title: Revisions to Payment Policies Under the Physician Fee Schedule for CY 2010 (CMS-1413-FC)
Abstract: This rule revises payment polices under the physician fee schedule, as well as other policy changes to payment under Part B.

Priority: Economically Significant
Agenda Stage of Rulemaking: Final Rule
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 405; 42 CFR 410 to 411; 42 CFR 413 to 414; 42 CFR 426 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Social Security Act, sec 1102; Social Security Act, sec 1871
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		11/01/2009

Timetable:

Action	Date	FR Cite
NPRM	07/13/2009	74 FR 33520
NPRM Comment Period End	08/31/2009	
Final Action	12/00/2009	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Federal
Federalism: No
Energy Affected: Undetermined
Related RINs: Related to 0938-AN04
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP41

View Related Documents

Title: Changes to the Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System for CY 2010 (CMS-1414-FC)

Abstract: This rule revises the Medicare hospital outpatient prospective payment system to implement applicable statutory requirements and changes arising from our continuing experience with this system and to implement certain related provisions of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). In addition, the rule describes changes to the amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the prospective payment system. The rule also changes the Ambulatory Surgical Center Payment System list of services and rates. These changes applicable to services furnished on or after January 1 annually.

Priority: Economically Significant Agenda Stage of Rulemaking: Final Rule
Major: Yes Unfunded Mandates: No
CFR Citation: 42 CFR 410; 42 CFR 410 to 413; 42 CFR 416; 42 CFR 419 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: BBA; BBA; BIPA; MMA; MMSEA; MIPPA; DRA; TRHCA
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		11/01/2009

Timetable:

Action	Date	FR Cite
NPRM	07/20/2009	74 FR 35231
NPRM Comment Period End	08/31/2009	
Final Action	12/00/2009	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: Federal
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)

Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP53

View Related Documents

Title: Children's Health Insurance Program (CHIP); Allotment Methodology and States' Fiscal Year 2009 CHIP Allotments (CMS-2291-F)

Abstract: This proposed rule describes the implementation of certain funding provisions under existing Medicaid laws, the Children's Health Insurance Program (CHIP) and recent legislation, and other related CHIP legislation. It proposes methodologies and procedures for determining States' fiscal year (FY) 2009 through FY 2013 allotments and payments

Priority: Economically Significant
Agenda Stage of Rulemaking: Final Rule
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 457.600 to 457.630 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1397dd(g); 42 USC 1397ee(g); secs 2104(e) and 2104(f) of the Social Security Act; CHIPRA of 2009 (PL 111-3)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		09/30/2009

Timetable:

Action	Date	FR Cite
NPRM	09/16/2009	74 FR 47517
NPRM Comment Period End	11/16/2009	
Final Action	02/00/2010	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: State
Federalism: No
Related RINs: Related to 0938-AP54
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP65

View Related Documents

Title: HIPAA Mental Health Parity and Addiction Equity Act of 2008 Amendments (CMS-4140-IFC)

Abstract: This rule implements statutory changes to the Public Health Services Act (PHSA) affecting the group health insurance markets and non-federal governmental plans, made by the Mental Health Parity and Addiction Equity Act of 2008.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: Undetermined
Unfunded Mandates: Undetermined
CFR Citation: 45 CFR 146.136 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Mental Health Parity and Addication Equity Act of 2008 (P.L.110-343)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	Interim final regulation	10/03/2009

Regulatory Plan:

Statement of Need: This rule is needed to implement MHPAEA, which expands the existing Mental Health parity law to

include substance abuse disorders and to require parity for mental health and substance abuse disorder benefits in treatment limitations and financial requirements.

Legal Basis: The Public Health Service Act and MHPAEA provide the authority to implement this rule.

Alternatives: Since this is a statutory requirement, no alternatives were considered.

Costs and Benefits: Promulgation of this rule will provide greater access to mental health and substance abuse disorder treatments by requiring group health plans to provide better coverage for those treatments.

Risks: This rule addresses the risk of individuals not being able to obtain necessary mental health and/or substance abuse disorder treatment because of limited health coverage for those treatments. By increasing access to treatment for mental health conditions and substance abuse disorders, this rule will also reduce the stigma experienced by millions of Americans who are afflicted with these conditions and allow them to remain in the workforce.

Timetable:

Action	Date	FR Cite
Request for Information	04/28/2009	74 FR 19155
RFI Comment Period End	05/28/2009	
Interim Final Rule	01/00/2010	
Interim Final Rule Comment Period End	03/00/2010	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Related RINs: Related to 1210-AB30; Related to 1545-BI70 Related Agencies: Joint: EBSA; Joint: IRS

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP66

View Related Documents

Title: Final and Preliminary Fiscal Year Disproportionate Share Hospital Payment Allotments and Institutions for Mental Disease Limits (CMS-2300-N)

Abstract: This final notice sets forth the States' final and preliminary fiscal year disproportionate share hospital (DSH) payment allotments and States' institutions for mental disease (IMD) DSH limits in the Medicaid program. This notice also announces provisions of the American Recovery and Reinvestment Act, which revises DSH allotments.

Priority: Other Significant

Agenda Stage of Rulemaking: Final Rule

Major: No

Unfunded Mandates: No

CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: Title XIX of the Social Security Act, sec 1923(f) and (h); American Recovery and Reinvestment Act of 2009 (PL 111-5)

Legal Deadline:

Action	Source	Description	Date
Other	Statutory	Detemination of Fiscal year DSH allotment and IMD DSH Limits	09/30/2009

Timetable:

Action	Date	FR Cite
Final Action	01/00/2010	

Regulatory Flexibility Analysis Required: No

Government Levels Affected: State

Small Entities Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP67

View Related Documents

Title: Multiple Source Drug Definition Amendment (CMS-2238-F2)

Abstract: This rule clarifies the October 7, 2008, final rule. This final rule clarification responds to a public comment that was not fully addressed in the final rule.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 447 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	12/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: No
Federalism: No
Energy Affected: No
Related RINs: Related to 0938-AP26

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP81

View Related Documents

Title: Part B Monthly Actuarial Rates, Monthly Premium Rates, and Annual Deductible Beginning January 1, 2011 (CMS-8042-N)

Abstract: This notice announces the monthly actuarial rates for aged (age 65 and over) and disabled (under age 65) enrollees in part B of Medicare for CY 2011. It also announces the monthly part B premiums and the Part B deductible during CY 2011.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: Undetermined
Unfunded Mandates: No

CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1395r; Social Secrity Act, sec 1839; MMA, sec 629; MMA, sec 811; DRA, sec 5111
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		09/30/2010

Timetable:

Action	Date	FR Cite
Final Action	09/00/2010	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP83

View Related Documents

Title: Inpatient Psychiatric Facility Prospective Payment System--Update for Rate Year Beginning July 1, 2010 (RY 2011) (CMS-1424-N)

Abstract: This notice will update the rates for Inpatient Psychiatric Facilities with discharges occurring during July 1, 2010 through June 30, 2011.

Priority: Other Significant
Major: Undetermined
Agenda Stage of Rulemaking: Final Rule
Unfunded Mandates: Undetermined
CFR Citation: 42 CFR 412.400, subpart N (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 106-113, sec 124 BBRA
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		05/01/2010

Timetable:

Action	Date	FR Cite
Final Action	05/00/2010	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: Business
Government Levels Affected: Local
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP85

View Related Documents

Title: Part A Premiums for CY 2011 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (CMS-8041-N)

Abstract: This notice announces the Hospital Insurance premium for calendar year 2011 under Medicare's Hospital Insurance program (Medicare part A) for the uninsured aged and for certain disabled individuals who have exhausted other entitlement.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1395i-2(d)(2); 42 USC 1395i-2a(d)(2); Social Security Act, sec 1818(d)(2); Social Security Act, sec 1818A(d)(2)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		09/30/2010

Timetable:

Action	Date	FR Cite
Final Action	09/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP86

View Related Documents

Title: Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for CY 2011 (CMS-8040-N)

Abstract: This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year 2011 under Medicare's Hospital Insurance program (Medicare part A). The Medicare statute specifies the formulae used to determine these amounts.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: Yes
Unfunded Mandates: No
CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1395e-2(d)(2); Social Security Act, sec 1813 (b)(2)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		09/15/2010

Timetable:

Action	Date	FR Cite

Final Action	09/00/2010	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AG81

View Related Documents

Title: Home Health Agency (HHA) Conditions of Participation (CoPs) (CMS-3819-P)

Abstract: This proposed rule would revise the existing Conditions of Participation (CoPs) that Home Health Agencies (HHAs) must meet to participate in the Medicare program. The requirements focus on the actual care delivered to patients by HHAs, reflect an interdisciplinary view of patient care, allow HHAs greater flexibility in meeting quality standards, and eliminate unnecessary procedural requirements. These changes are an integral part of our efforts to achieve broad-based improvements and measurements of the quality of care furnished through Federal programs while at the same time reducing procedural burdens on providers.

Priority: Other Significant
Major: No
Agenda Stage of Rulemaking: Long-term Action
Unfunded Mandates: No

CFR Citation: 42 CFR 409, 42 CFR 418, 42 CFR 484 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 42 USC 1302; 42 USC 1395x; 42 USC 1395cc(a); 42 USC 1395hh; 42 USC 1395bb
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Second NPRM	00/00/0000	
NPRM	03/10/1997	62 FR 11005
NPRM Comment Period End	06/09/1997	

Regulatory Flexibility Analysis Required: Undetermined
Small Entities Affected: Business; Organizations
Energy Affected: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AJ17

View Related Documents

Title: Medic Changes in Conditions of Participation Requirements and Payment Provisions for Rural Health Clinics and Federally Qualified Health Centers (CMS-1910-F2)

Abstract: This rule finalizes the provisions of the proposed rule published on June 27, 2008, which reissued provisions of the final rule that was published on December 24, 2003 and subsequently suspended. This final rule amends the Medicare certification requirements for rural health clinics (RHCs) as required by section 4205 of the Balanced Budget Act of 1997 by establishing location requirements for new and existing RHCs and criteria for exceptions to the location criteria for existing RHCs. It updates the regulations pertaining to RHC staffing requirements and waivers to the staffing requirements, and allows RHCs to contract with RHC nonphysician providers. It also revises the RHC and Federally Qualified Health Centers (FQHC) payment methodology to comply with statutory requirements. This final rule clarifies our policies on “commingling” of an RHC with another entity, and clarifies RHC and FQHC payment policies for services furnished to hospital patients and skilled nursing facility patients. It also requires RHCs and FQHCs to maintain and document an infection control process; post RHC or FQHC hours of clinical services; and updates the requirements under the emergency services standard and patient health records condition for certification (CfC) to reflect advancements in technology and treatment. It also replaces Urban Influence Codes (UICs) with Rural Urban Commuting Area Codes wherever UICs were used previously.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 405; 42 CFR 491 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302; 42 USC 1395hh; Deficit Reduction Act of 2005 (PL 109-171), sec 6083
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	MMA Section 902	06/27/2011

Timetable:

Action	Date	FR Cite
NPRM	02/28/2000	65 FR 10450
NPRM Comment Period End	04/28/2000	
Final Rule	12/24/2003	68 FR 74791
Interim Final Rule	09/22/2006	71 FR 55341
Interim Final Rule Comment Period End	11/21/2006	
Second NPRM	06/27/2008	73 FR 36463
NPRM Comment Period End	08/26/2008	
Final Action	06/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Federal
Small Entities Affected: Business
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AJ96

View Related Documents

Title: Use of Restraints and Seclusion in Residential Treatment Facilities Providing Inpatient Psychiatric Services to Individuals Under Age 21 (CMS-2065-F)

Abstract: This final rule addresses standards of practice that residential treatment facilities providing inpatient psychiatric services for individuals under age 21 must meet with regard to the use of restraints (including psychoactive drugs) and

seclusion.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 441 and 442; 42 CFR 483 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302; 42 USC 1396d
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Next Action Undetermined		
Interim Final Rule	01/22/2001	66 FR 7148
Interim Final Rule Effective	03/23/2001	
Interim Final Rule Comment Period End	03/23/2001	
60-Day Delay of Effective Date to 05/22/2001	03/21/2001	66 FR 15800
Interim Final Rule Amendment With Clarification	05/22/2001	66 FR 28110
Interim Final Rule Comment Period End	07/23/2001	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AK62

View Related Documents

Title: Electronic Claims Attachments Standards (CMS-0050-IFC)
Abstract: This rule sets forth electronic standards for health care claims attachments. The standards are required by the Health Insurance Portability and Accountability Act of 1996. They will be used to transmit clinical or administrative data for claims adjudication purposes.

Priority: Economically Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Yes
Unfunded Mandates: State, Local, Or Tribal Governments
CFR Citation: 45 CFR 162 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1320d-2(a)(2)(B)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		02/21/1999

Timetable:

Action	Date	FR Cite
Next Action Undetermined		
NPRM	09/23/2005	70 FR 55989
NPRM Comment Period End	11/22/2005	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: State
Federalism: Yes

Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AL88

View Related Documents

Title: Health Coverage Portability: Tolling Certain Time Periods and Interactions With Family and Medical Leave Act (CMS-2158-F)

Abstract: This final rule will clarify certain portability requirements for group health plans and issuers of health insurance coverage offered in connection with a group health plan. It also implements changes made to the Internal Revenue Code, the Employee Retirement Income Security Act, and the Public Health Service Act enacted as part of the Health Insurance Portability and Accountability Act of 1996.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 146.113; 45 CFR 146.115; 45 CFR 146.117; 45 CFR 146.120; 45 CFR 146.145 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 300gg; PL 104-191
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Next Action Undetermined		
NPRM	12/30/2004	69 FR 78800
NPRM Comment Period End	03/30/2005	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Federal; Local; State
Small Entities Affected: Business; Organizations
Federalism: Yes
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AN73

View Related Documents

Title: Revisions to the Requirements for Quality Improvement Organizations (CMS-3156-P)

Abstract: This proposed rule would revise existing regulations that govern Quality Improvement Organizations responsibilities under the Medicare program. These revisions are required by the Medicare, Medicaid, and Benefits Improvement and Protection Act of 2000 (BIPA); recommendations from the Institute of Medicine and the Government Accountability Office;

Agency initiatives related to Health Information Technology, Prevention, and beneficiary centeredness; and to improve program efficiencies. The proposed rule will also add to existing regulations certain established Medicare policies that currently are available only in policy memoranda and payment requirements.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 1154 to 1160 of the Social Security Act
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Next Action Undetermined		

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AO07

View Related Documents

Title: Payments for Service Provided Without Charge (Free Care) (CMS-2489-P)

Abstract: The proposed rule would clarify that Federal Financial Participation (FFP) is not available to States on behalf of Medicaid beneficiaries for Medicaid-covered services provided without charge (that is, free care) to individuals receiving the services. Free care means a particular service is available without charge to an individual who receives the service or to any third party on behalf of the individual.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 447 and 457 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: None
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Small Entities Affected: Governmental Jurisdictions
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO10

View Related Documents

Title: Medical Improvement Eligibility Group and Definition of Work (CMS-2143-P)

Abstract: In order to provide health services to employed individuals whose medical conditions have improved to the point where they are no longer eligible for disability benefits, this proposed rule would provide a definition of "medically determinable severe impairment" under the Ticket to Work and Work Incentives Improvement Act of 1999 (Ticket to Work). Under this definition, States can determine eligibility standards for the Medical Improvement Group authorized under the Ticket to Work law, thereby permitting individuals to retain their Medicaid coverage. Additionally, this proposed rule would give States offering Medicaid buy-in programs for employed individuals with disabilities the option of selecting a minimum work standard for participation.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 435 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 105-33, sec 4733 Balanced Budget Act of 1997; PL 106-170, sec 201 Ticket to Work and Work Incentives Improvement Act of 1999
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO34

View Related Documents

Title: Cytology Proficiency Testing (CMS-2252-F)

Abstract: This rule revises certain Clinical Laboratory Improvement Amendments (CLIA) of 1988 proficiency testing requirements for clinical laboratories offering cytology services and individuals examining gynecological cytology specimens. Revisions are also made to CMS approval requirements for programs offering proficiency testing for gynecologic cytology under (CLIA) of 1988 program. Evaluating the competency of each individual who examines gynecologic cytology specimens (pap smears) is required by Federal law and regulations. Identifying these individuals is essential in providing quality patient care.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No

CFR Citation: 42 CFR 493 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 263a, Clinical Laboratory Improvement Amendments of 1988; 42 USC 1395x, secs 1861s(15) to 1861s(17); of the Social Security Act
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	MMA Section 902	01/16/2012

Timetable:

Action	Date	FR Cite
NPRM	01/16/2009	74 FR 3264
NPRM Comment Period End	03/17/2009	
Final Action	01/00/2012	

Regulatory Flexibility Analysis Required: Undetermined
Small Entities Affected: Business
Energy Affected: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO50

View Related Documents

Title: Targeted Case Management (CMS-2237-F)

Abstract: This final rule revises current Medicaid regulations to incorporate changes made by section 6052 of the Deficit Reduction Act of 2005. It also will incorporate the provisions of the Final Rule published on June 30 2009,(74 FR 31183), which rescinded portions of the Interim Final Rule with comments. In addition, it incorporates provisions of the Consolidated Omnibus Budget Reconciliation Act of 1985, the Omnibus Budget Reconciliation Act of 1986, the Tax Reform Act of 1986, the Omnibus Budget Reconciliation Act of 1987, and the Technical and Miscellaneous Revenue Act of 1988, concerning case management and targeted case management services. This final rule will provide for optional coverage of case management services or targeted case management services furnished according to the Social Security Act. This final rule clarifies what Medicaid will pay for case management activities, when payment will not be consistent with proper and efficient operation of the Medicaid program, and when payment is not available.

Priority: Economically Significant
Major: Yes
Agenda Stage of Rulemaking: Long-term Action
Unfunded Mandates: No
CFR Citation: 42 CFR 431, 42 CFR 440 to 441 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Deficit Reduction Act of 2005; PL 109-171, sec 6052
Legal Deadline: Public Law 110-28 established a 1-year moratorium on rule until May 25, 2008. Public Law 110-252 extends the moratorium to March 31, 2009. Public Law 111-5 extends moratorium to June 30, 2009.

Action	Source	Description	Date
Other	Statutory		01/01/2006

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
Interim Final Rule	12/04/2007	72 FR 68077
Interim Final Rule Comment Period End	02/04/2008	
Interim Final Rule Effective	03/03/2008	

Regulatory Flexibility Analysis Required: Undetermined
Small Entities Affected: Governmental Jurisdictions
Energy Affected: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO53

View Related Documents

Title: Home and Community-Based Services (HCBS) State Plan Option (CMS-2249-F)

Abstract: This rule amends the Medicaid regulations to define and describe the home- and community-based State plan services implementing the new section 1915(i) of the Social Security Act as added by section 6086 of the Deficit Reduction Act of 2005.

Priority: Economically Significant
Major: Yes
Agenda Stage of Rulemaking: Long-term Action
Unfunded Mandates: No

CFR Citation: 42 CFR 431; 42 CFR 440 and 441 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Deficit Reduction Act of 2005; PL 109-171, sec 6086
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		01/01/2007

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
NPRM	04/04/2008	73 FR 18676
NPRM Comment Period End	06/03/2008	

Regulatory Flexibility Analysis Required: Governmental Jurisdictions
Federalism: No
Energy Affected: No
Government Levels Affected: State

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO87

View Related Documents

Title: Application of Certain Appeals Provisions to the Medicare Prescription Drug Appeals Process (CMS-4127-F)

Abstract: This rule implements the procedures that the Department of Health and Human Services will follow at the Administrative Law Judge and Medicare Appeals Council levels in deciding appeals brought by individuals who have enrolled in the Medicare prescription drug benefit program. In addition, it will implement the reopening procedures that will be followed at all levels of appeal.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 423 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 1102, 1860D-1 to 1860D-42, and 1871 of the Social Security Act (42 USC 1302, 1395w-101 to 1395w-152, and 1395hh)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	MMA Section 902	03/17/2011

Timetable:

Action	Date	FR Cite
NPRM	03/17/2008	73 FR 14341
NPRM Comment Period End	05/16/2008	
Final Action	03/00/2011	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AO90

View Related Documents

Title: Establishing Additional Provider and Supplier Requirements for Enrollment Standards and Related Issues (CMS-6036-F)
Abstract: This rule clarifies, expands, and adds to the existing enrollment requirements that Durable Medical Equipment and Prosthetics, Orthotics, and Supplies (DMEPOS) suppliers must meet to establish and maintain billing privileges in the Medicare program.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 424 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Sections 1102 and 1871 of the Act
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	MMA Section 902	01/25/2011

Timetable:

Action	Date	FR Cite
NPRM	01/25/2008	73 FR 4503
NPRM Comment Period End	03/25/2008	
Final Action	01/00/2011	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: Business
Energy Affected: No
Government Levels Affected: Federal
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO91

View Related Documents

Title: Emergency Preparedness Requirements for Medicare Participating Providers and Suppliers (CMS-3178-P)

Abstract: This rule proposes emergency preparedness requirements for a variety of providers and suppliers that participate in the Medicare and Medicaid programs, to ensure that if a natural or man-made disaster occurs, providers and suppliers can continue to meet the health care needs of their patients, residents, and clients.

Priority: Other Significant
Major: Undetermined
Agenda Stage of Rulemaking: Long-term Action
Unfunded Mandates: No

CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Not Yet Determined
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: Business
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP01

View Related Documents

Title: Establishing Additional Medicare Provider and Supplier Enrollment Safeguards (CMS-6045-P)

Abstract: This proposed rule would expand existing provider and supplier enrollment requirements to obtain or maintain Medicare billing privileges.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: Undetermined
CFR Citation: 42 CFR 424.40; 42 CFR 424.44; 42 CFR 424.525 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec. 4312(a) of BBA of 1997
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: Undetermined
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AP32

View Related Documents

Title: Requirements for Long-Term Care Facilities: Hospice Services (CMS-3140-P)

Abstract: This proposed rule would establish requirements that long-term care (LTC) facilities must have an agreement with hospice agencies when hospice care is provided in a long-term care facility to participate in the Medicare and Medicaid programs. We are proposing these new requirements to ensure that quality hospice care is provided to eligible residents.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 42 CFR 483 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302; 42 USC 1395hh
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Undetermined
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP57

View Related Documents

Title: ESRD Bundled Payment System (CMS-1418-F)

Abstract: This rule proposes to implement a bundled payment system for ESRD facilities by January 1, 2011, as required by section 153 of MIPAA.

Priority: Economically Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 410; 42 CFR 413 and 414 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 153 of MIPPA; sec 1881(b) of the Social Security Act
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		01/01/2011

Timetable:

Action	Date	FR Cite
NPRM	09/29/2009	74 FR 49922
NPRM Comment Period End	11/16/2009	
Final Action	09/00/2012	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Undetermined
Federalism: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP59

View Related Documents

Title: Limited Changes to the Competitive Acquisition of Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS)(CMS-1561-F)

Abstract: This final rule as mandated by section 154 of MIPPA requires the temporary delay of Round 1 of the DMEPOS Competitive Bidding Program such that a new competition occurs excluding certain services. Section 154 of MIPPA establishes other requirements for the program such as providing a process for giving suppliers feedback on missing financial documents and mandating the disclosure of subcontractors under a competitive bidding program. Section 154 also mandates additional refinements to be implemented before phasing in future rounds of the program.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 414 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: 42 USC 1302; 42 USC 1395hh; 42 USC 1395rr(b)(1)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	MMA section 902	01/16/2012

Timetable:

Action	Date	FR Cite
Interim Final Rule	01/16/2009	74 FR 2873
Interim Final Rule Comment Period End	03/17/2009	
Final Action	01/00/2012	

Regulatory Flexibility Analysis Required: Undetermined
Government Levels Affected: No
Federalism: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP61

View Related Documents

Title: Home and Community Based Services: Waiver Requirements (CMS-2296-P)
Abstract: This proposed rule would clarify that a State may design a waiver program that is cross-disability in nature and would include requirements for State-defined and CMS-approved criteria for characteristics of any home and community based setting. These changes would remove Federal barriers to the States' ability to design needs-based, person-centered HCBS Programs, rather than programs based solely upon an individual's diagnosis.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 300 to 310 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1396n(c)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	00/00/0000	
ANPRM	06/22/2009	74 FR 29453
ANPRM Comment Period End	08/21/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Undetermined
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP64

View Related Documents

Title: Medicare Advantage and Prescription Drug Benefit Programs; Payments to Sponsors of Retiree Prescription Drug Plans (CMS-4131-F2)

Abstract: This rule will specify whether Retiree Drug Subsidy plan sponsors can continue to choose to report either the "pass-through price" or the "lock in" price when reporting part D drug cost data.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 422 and 423 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302; 42 USC 1395w-101 to 1395w-152; 42 USC 1395hh
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	MMA section 902	01/12/2012

Timetable:

Action	Date	FR Cite
NPRM	01/12/2009	74 FR 1550
NPRM Comment Period End	03/13/2009	
Final Action	01/00/2012	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP69

View Related Documents

Title: Medicaid Program and Children's Health Insurance Program (CHIP); Revisions to the Medicaid Eligibility Quality Control and Payment Error Rate Measurement Programs (CMS-6150-F)

Abstract: This rule implements provisions from the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA) with regard to the Medicaid Eligibility Quality Control (MEQC) and Payment Error Rate Measurement (PERM) programs. This rule also codifies several procedural aspects of the process for estimating improper payments in Medicaid and the Children's Health Insurance Program (CHIP).

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 431, 447, 457 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: CHIPRA of 2009 (Pub.L. No: 111-3)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	07/15/2009	74 FR 34468
NPRM Comment Period End	08/14/2009	
Final Action	07/00/2012	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP72

View Related Documents

Title: State Flexibility for Medicaid Benefit Packages (CMS-2232-F4)

Abstract: This rule replaces the final rule published on December 3, 2008 (73 FR 73694) to implement provisions of the Deficit Reduction Act (DRA) of 2005. It also provides States increased flexibility under an approved State plan to define the scope of covered medical assistance by offering coverage of benchmark or benchmark-equivalent benefit packages to certain Medicaid-eligible individuals. In addition, this final rule responds to public comments on the February 22, 2008 proposed rule as well as public comments on the December 3, 2009 “final rule” which was temporarily delayed twice, once by an interim final rule with comment period published on February 2, 2009, and the second time by a final rule published on April 3, 2009, further delaying the effective date and reopening the comment period.

Priority: Economically Significant
Agenda Stage of Rulemaking: Long-term Action
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 440 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 109-171, sec 6044
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		03/31/2006

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: State
Federalism: No
Energy Affected: No
Related RINs: Related to 0938-AO48
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Department of Health and Human Services (HHS)

Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP73

View Related Documents

Title: Premiums and Cost Sharing (CMS-2244-FC)

Abstract: This final rule revises the November 25, 2008 final rule entitled, "Medicaid Programs; Premiums and Cost Sharing (73 FR 71828)," that implemented and interpreted provisions of the Deficit Reduction Act of 2005 (DRA) and the Tax Relief and Health Care Act of 2006 (TRHCA). In addition, this final rule responds to public comments on the November 25, 2008 final rule which were received after a notice was published on January 27, 2009 to reopen the comment period and temporarily delay for 60 days the effective date of the final rule and after a notice was published on March 27, 2009 to reopen the comment period and delay the final rule's effective date until December 31, 2009. This final rule also solicits public comments on revisions proposed to the final rule in response to the American Recovery and Reinvestment Act of 2009 (the Recovery Act), which was enacted during the temporary delay of the November 25, 2008 final rule.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 447; 42 CFR 457 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 109-171, sec 6041 and 6042; PL 109-432, sec 6043; PL 111-5; sec 5008 (a) of the Recovery Act
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		03/31/2006
Other	Statutory		01/01/2007

Timetable:

Action	Date	FR Cite
Interim Final Rule	00/00/0000	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State; Tribal
Small Entities Affected: No
Federalism: No
Energy Affected: Yes
Related RINs: Related to 0938-AO47
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AL26

View Related Documents

Title: Use of Restraints and Seclusion in Medicare and Medicaid Participating Facilities That Provide Inpatient or Residential Care (CMS-2130-P)

Abstract: This proposed rule would implement provisions of the Children's Health Act of 2000 (CHA) related to the use of restraints or seclusion for individuals receiving services in health care facilities that receive Federal funding. The rule would establish common terminology and basic expectations for the use of restraints and seclusion for health care facilities that furnish inpatient or residential care and receive Medicare or Medicaid funding.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 101; 42 CFR 418; 42 CFR 482 and 483; 42 CFR 485 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 106-554 (BIPA 2000 of the Children's Health Act)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Withdrawn	08/05/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: Business
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AN42

View Related Documents

Title: Limitation on Recoupment of Provider and Supplier Overpayments (CMS-6025-F)

Abstract: This rule implements a provision of the Medicare Prescription Drug Improvement and Modernization Act, which adjusts Medicare's ability to recover an overpayment when the Qualified Independent Contractor (QIC) receives a valid appeal from the provider or supplier. This rule defines the overpayments to which the limitation applies, how the limitation works in concert with the appeals process, and the change in Medicare's obligation to pay interest to a provider or supplier whose appeal is successful at levels above the QIC.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 405 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 1893(f)(2) of the Social Security Act added by sec 935 of the MMA
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	MMA Section 902	09/22/2009

Timetable:

Action	Date	FR Cite
NPRM	09/22/2006	71 FR 55404
NPRM Comment Period End	11/21/2006	
Final Action	09/16/2009	74 FR 47458

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AO81

View Related Documents

Title: Rehabilitation Services: State Plan Option (CMS-2261-P)

Abstract: This rule would amend the definition of Medicaid rehabilitative services in order to provide for important beneficiary protections such as a person-centered written rehabilitation plan and maintenance of case records. The rule also ensures the fiscal integrity of claimed Medicaid expenditures by clarifying the service definition and providing that Medicaid rehabilitative services must be coordinated with, but do not include services furnished by, other programs that are focused on social or educational development goals and are available as part of other services or programs. These services and programs include, but are not limited to, foster care, child welfare, education, child care, prevocational and vocational services, housing, parole and probation, juvenile justice, public guardianship, and any other non-Medicaid services from Federal, State, or local programs.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 440 to 441 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 1905(a)(13) of the Social Security Act
Legal Deadline: Public Law 110-28 established a 1-year moratorium on rule until May 25, 2008. Public Law 110-252 extends the moratorium to March 31, 2009.

Action	Source	Description	Date
Other	Statutory		03/31/2009

Timetable:

Action	Date	FR Cite
NPRM	08/13/2007	72 FR 45201
NPRM Comment Period End	10/12/2007	
Withdrawn	10/31/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AO95

View Related Documents

Title: Medicaid Graduate Medical Education (CMS-2279-F)

Abstract: As part of the President's 2008 Budget, this rule establishes that States may not include GME as a reimbursable cost or program under their approved Medicaid State Plan. The rule enhances fiscal integrity and improves accountability with respect to payment for medical services in the Medicaid program.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 438; 42 CFR 447 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: title XIX; Social Security Act
Legal Deadline: Public Law 110-28 established a 1-year moratorium on rule until May 25, 2008. Public Law 110-252 extended the moratorium to March 31, 2009.

Action	Source	Description	Date
Other	Statutory		03/31/2009

Timetable:

Action	Date	FR Cite
NPRM	05/23/2007	72 FR 28930
NPRM Comment Period End	06/22/2007	
Withdrawn	10/08/2009	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: State
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP10

View Related Documents

Title: Medicare Supplemental Policies (CMS-4084-P)
Abstract: This proposed rule would outline procedures for the States and CMS to certify the Medigap policies of private issuers. This proposed rule is authorized under the Medigap program.

Priority: Economically Significant Agenda Stage of Rulemaking: Completed Action
Major: Yes Unfunded Mandates: No
CFR Citation: 42 CFR 403.200 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 1882 of the Social Security Act
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Withdrawn	07/30/2009	

Regulatory Flexibility Analysis Required: No Government Levels Affected: State
Small Entities Affected: No Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP37

View Related Documents

Title: Genetic Information Nondiscrimination Act of 2008 (CMS-4137-IFC)
Abstract: This rule implements statutory changes to the PHSA affecting the group and individual health insurance markets, non-federal governmental plans, and Medicare supplemental insurance (Medigap) made by the Genetic Information

Nondiscrimination Act of 2008 (Pub. L. 110-223).

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 144.103; 45 CFR 146.121; 45 CFR 146.180; 45 CFR 148.120; 45 CFR 148.128; 45 CFR 148.210; 45 CFR 150.130; 45 CFR 150.301 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Genetic information Nondiscrimination Act of 2008 (PL 110-223), enacted May 21, 2008.
Legal Deadline: The statue requires regulations be issued 12 months after enactment, which was May 21, 2008, by the 3 agencies with shared jurisdiction-HHS, Treasury and Labor.

Action	Source	Description	Date
Other	Statutory	Interim final regulation	05/21/2009

Timetable:

Action	Date	FR Cite
ANPRM	10/10/2008	73 FR 60208
ANPRM Comment Period End	12/09/2008	
Interim Final Rule	10/07/2009	74 FR 51663

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Local; State
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AP39

View Related Documents

Title: Changes to the Hospital Inpatient and Long-Term Care Prospective Payment System for FY 2010 (CMS-1406-F)
Abstract: This rule revises the Medicare hospital inpatient and Long Term Care prospective payment systems (IPPS) for operating and capital-related costs to implement changes arising from our continuing experience with these systems.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 412 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Sec 1886(d) of the Social Security Act
Legal Deadline:

Action	Source	Description	Date
NPRM	Statutory		04/01/2009
Other	Statutory		08/01/2009

Timetable:

Action	Date	FR Cite
NPRM	05/22/2009	74 FR 24080
NPRM Comment Period End	06/30/2009	
Final Rule	08/27/2009	74 FR 43753

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: Federal
Federalism: No
Energy Affected: No

Related RINs: Related to 0938-AP32; Related to 0938-AP76

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP42

View Related Documents

Title: Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts for CY 2010 (CMS-8037-N)

Abstract: This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year 2010 under Medicare's Hospital Insurance program (Medicare part A). The Medicare statute specifies the formulae used to determine these amounts.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
Unfunded Mandates: No
CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1395e-2(b)(2); Social Security Act, sec 1813(b)(2)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		09/15/2009

Timetable:

Action	Date	FR Cite
Final Action	10/22/2009	74 FR 54579
Final Action Effective	01/01/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP43

View Related Documents

Title: Part A Premiums for CY 2010 for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement (CMS-8038-N)

Abstract: This notice announces the Hospital Insurance premium for calendar year 2010 under Medicare's Hospital Insurance

program (Medicare Part A) for the uninsured aged and for certain disabled individuals who have exhausted other entitlement.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
Unfunded Mandates: No
CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1395i-2(d)(2); 42 USC 1395i-2a(d)(2); Social Security Act, sec 1818(d)(2); Social Security Act, sec 1818A(d)(2)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		09/30/2009

Timetable:

Action	Date	FR Cite
Final Action	10/22/2009	74 FR 54581
Final Action Effective	01/01/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS)
RIN: 0938-AP45

View Related Documents

Title: Hospice Wage Index for FY 2010 (CMS-1420-F)
Abstract: This rule announces the annual update to the hospice wage index for FY 2010. The wage index is used to reflect local differences in wage levels.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 418 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1814(i)(1) and 1814(i)(2)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		08/01/2009

Timetable:

Action	Date	FR Cite
NPRM	04/24/2009	74 FR 18911
NPRM Comment Period End	06/22/2009	
Final Action	08/06/2009	74 FR 39383

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP46

View Related Documents

Title: Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities—Update for FY 2010 (CMS-1410-F)
Abstract: This rule updates the payment rates used under the SNF PPS beginning October 1, 2009.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 413, 409, and 483 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Social Security Act, sec 1888(e)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		07/31/2009

Timetable:

Action	Date	FR Cite
NPRM	05/12/2009	74 FR 22208
NPRM Comment Period End	06/30/2009	
Final Action	08/11/2009	74 FR 40287

Regulatory Flexibility Analysis Required: Business
Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP48

View Related Documents

Title: Part B Monthly Actuarial Rates, Monthly Premium Rates, and Annual Deductible Beginning January 1, 2010 (CMS-8039-N)
Abstract: This notice announces the monthly actuarial rates for aged (age 65 and over) and disabled (under age 65) enrollees in Part B of Medicare for CY 2010. It also announces the monthly Part B premiums and the Part B deductible during CY 2010.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action

Major: Yes Unfunded Mandates: No
CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1395r; Social Security Act, sec 1839; MMA, sec 629; MMA, sec 811; DRA, sec 5111; ...
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		09/30/2009

Timetable:

Action	Date	FR Cite
Final Action	10/22/2009	74 FR 54571
Final Action Effective	01/01/2010	

Regulatory Flexibility Analysis Required: No Government Levels Affected: No
Small Entities Affected: No Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP50

View Related Documents

Title: Inpatient Psychiatric Facility Prospective Payment System--Update for Rate Year Beginning July 1, 2009 (RY 2010) (CMS-1495-NC)
Abstract: This notice with comment period is necessary in order to update the rates for Inpatient Psychiatric Facilities with discharges occurring during July 1, 2009 through June 30, 2010.

Priority: Economically Significant Agenda Stage of Rulemaking: Completed Action
Major: Yes Unfunded Mandates: No
CFR Citation: 42 CFR 412.400, subpart N (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 106-113, sec 124 BBRA
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		05/01/2009

Timetable:

Action	Date	FR Cite
Final Action	05/01/2009	74 FR 20362

Regulatory Flexibility Analysis Required: No Government Levels Affected: Local
Small Entities Affected: Business Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP52

View Related Documents

Title: Revisions to the Medicare Advantage and Prescription Drug Programs (CMS-4138-F)

Abstract: This final rule revises the regulations governing the Medicare Advantage program (part C), and the prescription drug benefit program (part D).

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 417; 42 CFR 422 and 423 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1395w-28(f)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	MMA section 902	09/18/2011

Timetable:

Action	Date	FR Cite
Interim Final Rule	09/18/2008	73 FR 54225
Interim Final Rule	11/14/2008	73 FR 67406
Interim Final Rule Comment Period End	11/17/2008	
Interim Final Rule	01/16/2009	74 FR 2881
Merged With 0938-AP77	10/07/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Federal
Federalism: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP55

View Related Documents

Title: Home Health Prospective Payment System and Rate Update for CY 2010 (CMS-1560-F)

Abstract: This rule updates the 60-day national episode rate and the national per visit rate amounts under the Medicare Prospective Payment System for home health agencies, effective January 1, 2010.

Priority: Economically Significant
Agenda Stage of Rulemaking: Completed Action
Major: Yes
Unfunded Mandates: No
CFR Citation: 42 CFR 484 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Social Security Act, secs 1102 and 1871; 42 USC 1302 and 42 USC 1395(hh); Social Security Act, sec 1895; 42 USC 1395(fff)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		11/01/2009

Timetable:

Action	Date	FR Cite
NPRM	08/06/2009	74 FR 39435
NPRM Comment Period End	08/28/2009	
Final Action	11/10/2009	74 FR 58077
Final Action Effective	01/01/2010	

Regulatory Flexibility Analysis Required: Business Government Levels Affected: No
Federalism: No
Energy Affected: Undetermined
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP56

View Related Documents

Title: Prospective Payment System for Inpatient Rehabilitation Facilities for FY 2010 (CMS-1538-F)
Abstract: This rule updates rates for the prospective payment system for inpatient rehabilitation facilities for FY 2010.

Priority: Economically Significant Agenda Stage of Rulemaking: Completed Action
Major: Yes Unfunded Mandates: No
CFR Citation: 42 CFR 412 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Social Security Act, sec 1886(j); PL 106-554; PL 106-113
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		08/01/2009

Timetable:

Action	Date	FR Cite
NPRM	05/06/2009	74 FR 21052
NPRM Comment Period End	06/29/2009	
Final Action	08/13/2009	74 FR 40947

Regulatory Flexibility Analysis Required: Business Government Levels Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP62

View Related Documents

Title: Recognition of NAIC Model Standards for Regulation of Medicare Supplemental Insurance (CMS-4139-N)

Abstract: This notice describes changes made by the Genetic Information Nondiscrimination Act of 2008 (GINA) and the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) to section 1882 of the Social Security Act (the Act), which governs Medicare supplemental insurance. This notice also recognizes that the Model Regulation adopted by the National Association of Insurance Commissioners (NAIC) on September 24, 2008, is considered to be the applicable NAIC Model Regulation for purposes of section 1882 of the Act, subject to our clarifications that are set forth in this notice. Finally, the full text of the revised NAIC Model Regulation is included as an addendum to this notice.

Priority: Info./Admin./Other
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1395ss(s)(x)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	04/24/2009	74 FR 18808

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Federalism: No

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP74

View Related Documents

Title: Health Care-Related Taxes (CMS-2275-F2)

Abstract: This rule finalizes our proposal to delay enforcement of certain clarifications regarding standards for determining hold harmless arrangements in the final rule entitled, “Medicaid Program; Health Care-Related Taxes” from the expiration of a Congressional moratorium on enforcement from July 1, 2009 to June 30, 2010.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 443 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 109-432
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	06/30/2009	74 FR 31196

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Federalism: No
Related RINs: Related to 0938-AO80

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP75

View Related Documents

Title: Rescission of School-Based Services Final Rule, Outpatient Services Definition Final Rule, and Partial Rescission of Case Management Services Interm Final Rule (CMS-2287-F2)

Abstract: This rule finalizes our proposal to rescind the December 28, 2007 final rule entitled, "Elimination of Reimbursement under Medicaid for School Administration Expenditures and Costs Related to Transportation of School-Age Children Between Home and School"; the November 7, 2008, final rule entitled, "Clarification of Outpatient Hospital Facility (Including Outpatient Hospital Clinic) Services Definition"; and certain provisions of the December 4, 2007 interim final rule entitled, "Optional State Plan Case Management Services." These regulations have been the subject of Congressional moratoria and have not yet been implemented (or, with respect to the case management interim final rule, have only been partially implemented) by CMS. In light of concerns raised about the adverse effects that could result from these regulations, in particular, the potential restrictions on services available to beneficiaries and the lack of clear evidence demonstrating that the approaches taken in the regulations are warranted, CMS is rescinding the two final rules in full, and partially rescinding the interim final rule. Rescinding these provisions will permit further opportunity to determine the best approach to further the objectives of the Medicaid program in providing necessary health benefits coverage to needy individuals.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 431 and 433; 42 CFR 441 and 440 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1395hh
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Final Action	06/30/2009	74 FR 31183

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Federalism: No
Related RINs: Related to 0938-AP13; Related to 0938-AO17; Related to 0938-AO50

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Department of Health and Human Services (HHS)
Centers for Medicare & Medicaid Services (CMS) RIN: 0938-AP76

View Related Documents

Title: Revisions to FY 2009 Medicare Severity--Long-Term Care--Diagnosis-Related Group Weights (CMS-1337-IFC)

Abstract: This interim final rule with comment will implement corrected MS -LTC-DRG weights for the Long-Term Acute Care Prospective Payment System for Federal fiscal year 2009. These corrected weights will apply to payments to affected providers effective on the date of display of the interim final rule with comment.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 412 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 1886(d)(1)(B)(iv); sec 123 of the Balanced Budget Refinement Act of 1999 (BBRA) as amended by section 307(b) Benefits Improvement and Protection; Act of 2000 (BIPA)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Interim Final Rule	06/03/2009	74 FR 26546

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Federal
Federalism: No
Related RINs: Merge with 0938-AP39

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Department of Health and Human Services (HHS)
Office of Public Health and Science (OPHS)
RIN: 0940-AA01

View Related Documents

Title: Public Health Service Standards for the Protection of Research Misconduct Whistleblowers

Abstract: To implement section 493(e) of the Public Health Service Act (added by sec. 163 of the National Institutes of Health Revitalization Act of 1993, Pub. L. 103-43), the Department is proposing to add a new part 94 to title 42 of the Code of Federal Regulations. Under this proposed regulation, covered institutions must follow certain requirements for preventing and responding to occurrences of retaliation against whistleblowers. The purpose of this part is to protect: 1) Persons who make a good faith allegation that a covered institution or member thereof engaged in, or failed to respond adequately to an allegation of research misconduct; and 2) persons who cooperate in good faith with an investigation of research misconduct.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 94 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 216; 42 USC 241; 42 USC 289b
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	11/28/2000	65 FR 70830
NPRM Comment Period End	01/29/2001	
Final Action	12/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No

Related RINs: Related to 0940-AA04

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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC36

View Related Documents

Title: Revised Head Start Performance Standards, Target Population and Conversion

Abstract: This proposed rule would modify Head Start program performance standards as necessary to reflect changes enacted in the Head Start for School Readiness Act of 2007. Changes could affect performance standards related to health, parental involvement, nutritional and social services, transitional and other services, education performance standards and measures, and standards related to family service workers, home visitors, and the condition and location of facilities. As required by statute, regulations will be drafted following consultations with experts and consideration of the National Academy of Sciences study on Developmental Outcomes and Assessments for Young Children. The proposed rule also will address provisions: (1) allowing grantees to request conversion of Head Start slots to serve additional infant and toddler age children; (2) addressing children with disabilities; and (3) removing barriers to serving homeless children.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 9801 et seq
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	07/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC39

View Related Documents

Title: Interim Assistance for Trafficking Victims Under the Trafficking Victims Reauthorization Act of 2008

Abstract: The William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 (the Act), Public Law 110-457, revised and reauthorized the Trafficking Victims Protection Program. This rule would implement changes to the program that authorize interim assistance to child victims under section 212(a) of the Act.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule

Major: No Unfunded Mandates: No
CFR Citation: 45 CFR 404 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 22 USC 7101 note, William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	08/00/2010	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: Governmental Jurisdictions; Organizations
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Government Levels Affected: Local; State
Federalism: No

Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC42

View Related Documents

Title: Implementation of the Unaccompanied Alien Children (UAC) Provisions of the Trafficking Victims Reauthorization Act of 2008

Abstract: The William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 (the Act), Public Law 110-457, made significant changes concerning the care and placement of unaccompanied alien children while they are in the care of the Office of Refugee Resettlement (ORR). This rule would implement changes to the program under section 235 of the Act addressing issues like age determinations, placement determinations, suitability assessments and home studies. This rule also will address provisions of the Flores settlement agreement that were not addressed in Public Law 110-457.

Priority: Other Significant Agenda Stage of Rulemaking: Proposed Rule
Major: No Unfunded Mandates: No
CFR Citation: 45 CFR 410 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 22 USC 7101 note, William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	11/00/2010	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
Agency Contact: Kenneth Tota
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Government Levels Affected: Federal
Federalism: No

Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC43

View Related Documents

Title: Performance Standards for Runaway and Homeless Youth Grantees

Abstract: This rule would implement section VIII of the Reconnecting Homeless Youth Act of 2008 requiring the Secretary of Health and Human Services to issue rules that specify performance standards for public and nonprofit private entities that receive grants under the Runaway and Homeless Youth Program.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 1351 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Reconnecting Homeless Youth Act, PL 110-378
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	Statutory	10/08/2009

Timetable:

Action	Date	FR Cite
NPRM	04/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Local; State; Tribal
Small Entities Affected: Organizations
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC44

View Related Documents

Title: Recompetition of Head Start Grantees

Abstract: This rule would implement provisions of the Improving Head Start for School Readiness Act of 2007, (Pub. L. 110-134) requiring the Secretary to develop a system that will evaluate each grantee's performance every five years to determine which grantees are providing services of such high quality that they should be given another five year grant without needing to recompete for the grant.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: S/B Improving Head Start for School Readiness Act of 2007, PL 110-134
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	07/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC45

View Related Documents

Title: Safeguarding Child Support Information

Abstract: This rule would modify provisions of the final rule published September 26, 2008 (73 FR 56422) to address legislation enacted subsequent to publication and other matters.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 302, 303, and 307 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	01/00/2010	
Final Action	12/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC28

View Related Documents

Title: Limitation on Use of Funds Made Available To Monitor and Combat Trafficking In Persons

Abstract: This rule will implement provisions of the Trafficking Victims Protection Act of 2000 which prohibits programs from using trafficking funds to promote, support, or advocate the legalization or practice of prostitution and makes ineligible for funding any organization that promotes, supports, or advocates the legalization or the practice of prostitution unless the organization provides services to individuals solely after they are no longer engaged in such activities.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 404 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 22 USC ch 78 Trafficking Victims Protection Act
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	02/26/2008	73 FR 10210
NPRM Comment Period End	04/28/2008	
Final Action	06/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: Business
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF)
RIN: 0970-AC32

View Related Documents

Title: Computerized Tribal IV-D System and Office Automation

Abstract: This rule would amend the Federal child support regulation by adding a new part 310, Computerized Tribal IV-D System and Office Automation. The rule would set forth the conditions for Federal funding and requirements governing computerized Tribal IV-D systems and office automation.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 104-193
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	06/11/2008	73 FR 33048
NPRM Comment Period End	08/11/2008	
Final Action	02/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Federal; Tribal
Federalism: No

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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF)
RIN: 0970-AC33

View Related Documents

Title: Advance Planning Document Reform

Abstract: This rule updates existing regulations at 45 CFR 95 to make conforming changes reflecting transfer of HHS grant

authority from 45 CFR 74 to part 92; to make technical updates to accurately reflect current terminology such as HCFA to CMS; and to make revisions designed to reduce the amount of Federal oversight and monitoring based on risk.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 95 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 5 USC 301, 42 USC 622(b); 42 USC 629(b); 42 USC 629b(a), 42 USC 652(a), 42 USC 654(a), 42 USC 671(a), 42 USC 1302, 42 USC 1396(a)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	03/07/2008	73 FR 12341
NPRM Comment Period End	05/06/2008	
Final Action	04/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: No
Federalism: No
Energy Affected: No
RIN Information URL: regulations.acf.hhs.gov
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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC37

View Related Documents

Title: Intergovernmental Child Support Enforcement
Abstract: This regulation would revise Federal requirements for establishing and enforcing intergovernmental support obligations in child support enforcement program cases receiving services under title IV-D of the Social Security Act (the Act). The changes would: revise current interstate requirements to apply to case processing in all intergovernmental cases; require the responding State IV-D agency to pay the cost of genetic testing; clarify responsibility for determining in which State tribunal a controlling order determination is made where multiple support orders exist; recognize and incorporate electronic communication advancements; and make conforming changes to the Federal substantial-compliance audit and State self-assessment requirements.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 301 to 303; 45 CFR 305; 45 CFR 308 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/08/2008	73 FR 74408
NPRM Comment Period End	02/06/2009	
Final Action	09/00/2010	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
Government Levels Affected: Local; State; Tribal
Federalism: No

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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC40

View Related Documents

Title: Use of TANF Funds Carried Over From Prior Year

Abstract: This rule would implement section 2103 of the American Recovery and Reinvestment Act of 2009 to provide that a State or Tribe may use reserve Temporary Assistance for Needy Families (TANF) grant funds for any benefit or service activity under the TANF program.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 263 and 286 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: American Recovery and Reinvestment Act of 2009
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Interim Final Rule	05/27/2009	74 FR 25161
Interim Final Rule Comment Period End	07/27/2009	
Final Action	12/00/2009	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
Government Levels Affected: Local; State; Tribal
Federalism: No

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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF) RIN: 0970-AC41

View Related Documents

Title: Tribal Child Welfare

Abstract: This rule would implement title III, Tribal Foster Care and Adoption Access, of the Fostering Connections to Success and Increasing Adoptions Act of 2008 (the Act). Under section 301 of that Act, the Secretary is required to promulgate interim final regulations to carry out the title III provisions, including providing for transfer of responsibility for the placement and

care of a child under a State plan approved under section 471 of the Social Security Act to a tribal plan. This rule also will address in-kind expenditures from third-party sources for purposes of determining the non-Federal share of administrative and training expenditures as required in section 301 of the Act.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 1355, 1356 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Fostering Connections to Success and Increasing Adoptions Act of 2008
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	Statutory	10/09/2009

Timetable:

Action	Date	FR Cite
Interim Final Rule	07/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State; Tribal
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Administration for Children and Families (ACF)
RIN: 0970-AC35

View Related Documents

Title: Target Population and Conversion
Abstract: This proposed rule will address provisions from the Improving Head Start for School Readiness Act of 2007, (Pub. L. 110-134), allowing grantees to request conversion of Head Start slots to serve additional infant and toddler age children upon application, and align Head Start program regulations with new requirements affecting children with disabilities. This rule also would address policies and procedures for removing barriers to serving homeless children and make conforming changes to reflect Public Law 110-134.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 1301; 45 CFR 1305 and 1306; 45 CFR 1308 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 9801 et seq
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Withdrawn	09/03/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Office of the Secretary (OS) RIN: 0991-AB03

View Related Documents

Title: Revisions to Regulations Addressing the OIG's Authority To Impose Civil Money Penalties and Assessments

Abstract: This proposed rule would revise part 1003, addressing the Office of Inspector General's authority to propose the imposition of civil money penalties and assessments by reorganizing and simplifying existing regulatory text and eliminating obsolete references contained in the current regulations. Among the proposed revisions, this rule would establish separate subparts within part 1003 for various categories of violations; clarify the availability of exclusion for certain violations in addition to civil money penalties and assessments; date various references to managed care organization authorities; and clarify the application of section 1140 of the Social Security Act with respect to the misuse of certain Departmental symbols, emblems, or names through Internet and e-mail communications.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 1003 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1320a-7a; 42 USC 1395mm; 42 USC 1395w-27; 42 USC 1396b; PL 99-660; PL 107-188
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/00/2010	
NPRM Comment Period End	06/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
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Department of Health and Human Services (HHS)
Office of the Secretary (OS) RIN: 0991-AB33

View Related Documents

Title: Revisions to the Office of Inspector General's (OIG) Exclusion Authorities

Abstract: In accordance with section 949 of the Medicare Prescription Drug Improvement and Modernization Act of 2003, this rule would revise the OIG's exclusion authority to permit any Federal health care program to request a waiver of an OIG exclusion imposed under sections 1128(a)(1), 1128(a)(3), or 1128(a)(4) of the Social Security Act. In addition, the proposed rule would revise current exclusion provisions in 42 CFR parts 1001, 1002, and 1005 to further clarify OIG's existing exclusion authorities.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 1001 and 1002; 42 CFR 1005 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 108-173, sec 949; PL 105-33, sec 4331; Social Security Act, sec 1128

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/00/2010	
NPRM Comment Period End	06/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Office of the Secretary (OS)
RIN: 0991-AB41

View Related Documents

Title: Revisions to OIG Regulations Governing State Medicaid Fraud Control Units
Abstract: This proposed rule would revise and update part 1007, addressing the Office of Inspector General's authority regarding the requirements and procedures for establishing and operating a State Medicaid Fraud Control Unit. The current regulations were originally promulgated in 1978 and recodified in 1992.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: Undetermined
CFR Citation: 42 CFR 1007 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302, 42 USC 1396b(a)(6), 42 USC 1396b(b)(3); 42 USC 1396b(q)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	04/00/2010	
NPRM Comment Period End	06/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Small Entities Affected: No
Federalism: Undetermined
Energy Affected: No
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Department of Health and Human Services (HHS)
Office of the Secretary (OS)
RIN: 0991-AB45

View Related Documents

Title: Travel Reimbursement for Medicare Hearings Before Administrative Law Judges (ALJs) of the Office of Medicare Hearings and Appeals
Abstract: The Office of Medicare Hearings and Appeals (OMHA) is proposing a rule to implement the provisions of section 1817(i) of the Social Security Act. Section 1817(i) allows expenditures from the Trust fund for the payment of travel expenses for

certain individuals that participate in a hearing before an Administrative Law Judge (ALJ) with respect to any determination under title XVIII of the Social Security Act. Section 1817(i) requires the Secretary to enact regulations that establish the eligibility and procedures for reimbursement.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 1817(i) and 1871 of the Social Security Act; 42 USC 1395i, 1395hh
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	01/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Undetermined
Small Entities Affected: No
Federalism: Undetermined
Energy Affected: No
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Department of Health and Human Services (HHS)
Office of the Secretary (OS)
RIN: 0991-AB51

View Related Documents

Title: Principles for Determining Costs at Hospitals Under Federal Grants, Contracts, and Cooperative Agreements
Abstract: This notice of proposed rulemaking will publish for a thirty-day comment period revisions to 45 CFR part 74, appendix E: Principles for Determining Costs at Hospitals Under Federal Grants, Contracts, and Cooperative Agreements (hereinafter referred to as the Hospital Cost Principles or HCP). It is the culmination of a comprehensive review process begun in 2005 and incorporates relevant elements of the Office of Management and Budget circulars for Colleges and Universities (OMB Circular A-21), Non-Profit Institutions (OMB Circular A-122), and State and Local Governments (OMB Circular A-87). These other principles were revised by OMB in the early 1990's, but the Hospital Cost Principles were not.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 45 CFR 74, appendix E (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Not Yet Determined
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Local; State
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Office of the Secretary (OS) RIN: 0991-AB52

View Related Documents

Title: Rescission of Interest Prohibition in the Principles for Determining Costs at Hospitals Under Federal Grants, Contracts, and Cooperative Agreements

Abstract: This Notice of Proposed Rulemaking (NPRM) would rescind the current prohibition against interest as an allowable expense. The recision applies only to interest endured for new construction, facility acquisitions and interest debt to acquire or replace facility acquisitions. It makes the Hospital Cost Principles consistent with the Office of Management and Budget circulars for Colleges and Universities (OMB Circular A-21), Non-Profit Institutions (OMB Circular A-122), and State and Local Governments (OMB Circular A-87) concerning the allowance of interest debt. These other principles were revised in the early 1990's, but the Hospital Cost Principles were not. In 2000, the current interest request waiver process was established as a temporary practice to align the Hospital Cost Principles with A-21 and A-87 until a permanent revision could be published. Since then, twelve such waivers have been granted by the Department. The standards in this NPRM would be the same as those in A-21 and A-87. This NPRM establish the Department of Health and Human Services as the proponent agency for appendix E of 45 CFR part 74 with inherent responsibility to review, approve, and deny requests for waiver to Hospital Cost Principles.

Priority: Routine and Frequent
Agenda Stage of Rulemaking: Proposed Rule
Major: Undetermined
Unfunded Mandates: No
CFR Citation: 42 CFR 74 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Not Yet Determined
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	01/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Local; State
Federalism: No
Energy Affected: No
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Department of Health and Human Services (HHS)
Office of the Secretary (OS) RIN: 0991-AB54

View Related Documents

Title: Standards for Privacy of Individually Identifiable Health Information; Modifications to the HIPAA Privacy Rule Required by the Genetic Information Nondiscrimination Act of 2008

Abstract: The Department of Health and Human Services Office for Civil Rights will issue rules to implement the modifications to the HIPAA Privacy Rule required by section 105 of the Genetic Information Nondiscrimination Act of 2008. These rules will prohibit certain health plans from using or disclosing genetic information about an individual for underwriting purposes.

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 160; 45 CFR 164 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1320d-9
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		05/21/2009

Timetable:

Action	Date	FR Cite
NPRM	10/07/2009	74 FR 51698
NPRM Comment Period End	12/07/2009	

Regulatory Flexibility Analysis Required: No Government Levels Affected: No

Federalism: No

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Department of Health and Human Services (HHS)
Office of the Secretary (OS) RIN: 0991-AB57

View Related Documents

Title: Standards for Privacy of Individually Identifiable Health Information; Modifications to the HIPAA Privacy Rule Under the Health Information Technology for Economic and Clinical Health Act

Abstract: The Department of Health and Human Services Office for Civil Rights will issue rules to modify the HIPAA Privacy Rule as necessary to implement the accounting provisions of Section 13405(c) of the Health Information Technology for Economic and Clinical Health Act (Title XIII of the American Recovery and Reinvestment Act of 2009).

Priority: Other Significant Agenda Stage of Rulemaking: Proposed Rule

Major: Undetermined Unfunded Mandates: Undetermined

CFR Citation: 45 CFR 160; 45 CFR 164 (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: PL 111-5, secs 13400 to 13410

Legal Deadline:

Action	Source	Description	Date
NPRM	Statutory		02/17/2010

Regulatory Plan:

Statement of Need: The Office for Civil Rights will issue rules to modify the HIPAA Privacy rule to implement the privacy provisions in sections 13400-13410 of the Health Information technology for economic and clinical health act (Title XIII of division a of the American Recovery and Reinvestment Act of 2009, Pub. L. 111-5). these regulations will improve the privacy and security protection of health information.

Legal Basis: Subtitle D of the Health Information Technology for Economic and Clinical Health Act (Title XIII of the American Recovery and Reinvestment Act of 2009) requires the Office for Civil Rights to modify certain provisions of the HIPAA Privacy and Security Rules to implement sections 13400-13410 of the Act.

Alternatives: The Office for Civil Rights is statutorily mandated to make modifications to the HIPAA Privacy and Security Rules to implement the privacy provisions at sections 13400-13410 of the Health Information Technology for Economic and Clinical Health Act (Title XIII of the American Recovery and Reinvestment Act of 2009).

Costs and Benefits: These modifications to the HIPAA Privacy Rule are intended to benefit health care consumers by strengthening the privacy and security protections that govern how their health information is used and disclosed by HIPAA covered entities and their business associates. The Agency believes that there may be costs associated with the regulations that will affect HIPAA covered entities and their business associates. These may include costs to redraft existing business associate contracts as well as for the training on new policies and procedures as a result of these regulations.

Risks:

Timetable:

Action	Date	FR Cite
NPRM	12/00/2009	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: State

Federalism: Yes

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Department of Health and Human Services (HHS)
Office of the Secretary (OS)

RIN: 0991-AB59

View Related Documents

Title: Proposed Establishment of Certification Programs for Health Information Technology

Abstract: As specified in section 3001(c)(5) of the Health Information Technology for Economic and Clinical Health Act, this rule explains the proposed establishment of certification programs for the voluntary certification of health information technology.

Priority: Other Significant

Agenda Stage of Rulemaking: Proposed Rule

Major: Undetermined

Unfunded Mandates: Undetermined

CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: Not Yet Determined

Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/00/2009	

Regulatory Flexibility Analysis Required: Undetermined

Government Levels Affected: Undetermined

Federalism: Undetermined

Energy Affected: Undetermined

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Department of Health and Human Services (HHS)
Office of the Secretary (OS)

RIN: 0991-AB16

View Related Documents

Title: Safe Harbor for Waiver of Beneficiary Co-Insurance and Deductible Amounts for a Medicare SELECT Policy

Abstract: This final rule will expand the existing safe harbor for certain waivers of beneficiary co-insurance and deductible amounts to benefit the policyholders of Medicare SELECT supplemental insurance. Specifically, the amended safe harbor will

protect waivers of co-insurance and deductible amounts under part A or part B of the Medicare program owed by beneficiaries covered by a Medicare SELECT policy issued in accordance with section 1882(t)(1) of the Social Security Act, if the waiver is in accordance with a price reduction agreement covering such policyholders between the Medicare SELECT issuer and the provider or supplier offering the waiver.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 1001 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 100-93, sec 14(a)
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	09/25/2002	67 FR 60202
NPRM Comment Period End	10/25/2002	
Final Action	02/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
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Department of Health and Human Services (HHS)
Office of the Secretary (OS)
RIN: 0991-AB42

View Related Documents

Title: Revisions to Procedures for the Departmental Appeals Board and Other Departmental Hearings
Abstract: This Final Rule would amend Departmental regulations governing administrative review by the Departmental Appeals Board (DAB) to ensure that the final administrative decision of the Department reflects the considered judgment of the Secretary. Specifically, it would provide a process for Secretarial review of DAB decisions, and would make clear that the DAB must follow published guidance. The NPRM would address DAB review under a number of different authorities, and would also make technical changes to the DAB's regulations.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: Not Yet Determined
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	12/28/2007	72 FR 73708
NPRM Comment Period End	01/28/2008	
Final Action	01/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Small Entities Affected: No
Federalism: No
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Department of Health and Human Services (HHS)
Office of the Secretary (OS) RIN: 0991-AB55

View Related Documents

Title: HIPAA Administrative Simplification; Modifications to the HIPAA Enforcement Rule

Abstract: The Department of Health and Human Services will issue rules to modify the HIPAA Administrative Simplification Enforcement Rule as needed to implement the provisions of section 13410 of the Health Information Technology for Economic and Clinical Health Act (Title XIII of the American Recovery and Reinvestment Act of 2009).

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 160 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-5, sec 13410
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Interim Final Rule	10/30/2009	74 FR 56123
Interim Final Rule Comment Period End	12/29/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Office of the Secretary (OS) RIN: 0991-AB56

View Related Documents

Title: HIPAA Administrative Simplification; Notification in the Case of Breach

Abstract: The Department will issue rules for HIPAA covered entities and business associates with respect to breach notification of unsecured protected health information, as required by section 13402 of the Health Information Technology for Economic and Clinical Health Act (title XIII of the American Recovery and Reinvestment Act of 2009).

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 160; 45 CFR 164 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 111-5, sec 13402
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		08/17/2009

Timetable:

Action	Date	FR Cite
Interim Final Rule	08/24/2009	74 FR 42740
Interim Final Rule Comment Period End	10/24/2009	
Final Action	02/00/2010	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Office of the Secretary (OS)
RIN: 0991-AB58

View Related Documents

Title: Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology

Abstract: The Department of Health and Human Services (HHS), Office of the National Coordinator for Health Information Technology, will issue an interim final rule with a request for comments to adopt an initial set of standards, implementation specifications, and certification criteria, as required by section 3004(b)(1) of the Public Health Service Act.

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 170 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 300jj-14
Legal Deadline:

Action	Source	Description	Date
Other	Statutory	Interim final rule	12/31/2009

Regulatory Plan:

Statement of Need: This interim final rule represents the first round of what will be an incremental approach to adopting standards, implementation specifications, and certification criteria for health information technology. The certification criteria adopted in this initial set establish the technical capabilities and related standards that certified electronic health record (EHR) technology will need to include in support of the Medicare and Medicaid EHR Incentive Programs.

Legal Basis: Section 3004(b)(1) of the PHSA requires the Secretary to adopt an initial set of standards, implementation specifications, and certification criteria by 12/31/09. This interim final rule is being published to meet this requirement.

Alternatives: No alternatives are available because the issuance of this regulation is required by statute.

Costs and Benefits: We anticipate that there will be costs incurred as a result of the interim final rule to prepare health information technology for certification. Benefits include improved interoperability and increased health information technology adoption.

Risks:

Timetable:

Action	Date	FR Cite
Interim Final Rule	12/00/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: Federal
Small Entities Affected: No
Federalism: No
Energy Affected: No

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Department of Health and Human Services (HHS)
Office of the Secretary (OS) RIN: 0991-AA91

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Title: Shared Risk Exception to the Safe Harbor Provisions

Abstract: This final rule establishes a new safe harbor for risk-sharing arrangements under the Federal health care programs' anti-kickback provisions. The rule sets forth an exception from liability for remuneration between an eligible organization and an individual or entity providing items or services in accordance with a written agreement between these parties. The rule allows remuneration between an organization and an individual or entity if a written agreement places the individual or entity at "substantial financial risk" for the cost or utilization of the items or services that the individual or entity is obligated to provide.

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 1001 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 42 USC 1302; 42 USC 1320a-7b; 42 USC 1395hh; PL 104-191, sec 216(b)
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		01/01/1997

Timetable:

Action	Date	FR Cite
Final Action	00/00/0000	
ANPRM	05/23/1997	62 FR 28410
ANPRM Comment Period End	06/09/1997	
Interim Final Rule	11/19/1999	64 FR 63504
Interim Final Rule Comment Period End	01/18/2000	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No
Federalism: No
Related RINs: Related to 0991-AB06
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Department of Health and Human Services (HHS)
Office of the Secretary (OS) RIN: 0991-AB49

View Related Documents

Title: Rescission of the Regulation Entitled Ensuring That Department of Health and Human Services Funds Do Not Support Coercive of Discriminatory Policies or Practices in Violation of Federal Law

Abstract: The Department of Health and Human Services proposes to rescind the December 19, 2008 final rule entitled "Ensuring That Department of Health and Human Services Funds Do Not Support Coercive or Discriminatory Policies or Practices in Violation of Federal Law," 73 FR 78072.

Priority: Other Significant
Agenda Stage of Rulemaking: Long-term Action
Major: No
Unfunded Mandates: No
CFR Citation: Not Yet Determined (To search for a specific CFR, visit the Code of Federal Regulations)

Legal Authority: Not Yet Determined
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Undetermined	00/00/0000	
NPRM	03/10/2009	74 FR 10207
NPRM Comment Period End	04/09/2009	

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)
Office of the Secretary (OS) RIN: 0991-AB44

View Related Documents

Title: State Long-Term Care Partnership Program; Reporting Requirements for Insurers

Abstract: This Final Rule will establish the proposed reporting requirements that must be met by private insurers that issue qualified long-term care insurance policies in States participating in the State Long-Term Care Partnership Program established under the Deficit Reduction Act (DRA) of 2005 (Pub. L. 109-171). Section 6021 of the Deficit Reduction Act of 2005 requires that the Secretary specify a set of reporting requirements and collect data from insurers on qualifying long-term care insurance policies issued under the program and the subsequent use of the benefits under these policies

Priority: Other Significant
Major: No
Agenda Stage of Rulemaking: Completed Action
Unfunded Mandates: No

CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: sec 1917(b)(1)(C) (iii)(VI), Social Security Act
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	05/23/2008	73 FR 30030
NPRM Comment Period End	07/22/2008	
Final Action	12/18/2008	73 FR 76960

Regulatory Flexibility Analysis Required: No
Small Entities Affected: No
Energy Affected: No
Government Levels Affected: No
Federalism: No

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Department of Health and Human Services (HHS)

Office of the Secretary (OS) RIN: 0991-AB47

View Related Documents

Title: State Long-Term Care Partnership Program: State Reciprocity Standard

Abstract: Under section 6021 of Public Law 109-171, the Deficit Reduction Act of 2005 (DRA), States may provide asset disregards (and related estate recovery offsets) for Medicaid applicants who receive benefits under qualified long term care insurance policies (Partnership policies) that were purchased in the same State. This notice sets forth standards for states that choose to enter into a reciprocity agreement under section 6021(b) of the DRA, under which they agree to provide the same disregards and offsets for qualified Partnership policies that a Medicaid applicant purchased in another State that participates in the reciprocity agreement.

Priority: Other Significant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: None (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: PL 109-171, sec 6021
Legal Deadline: None

Timetable:

Action	Date	FR Cite
Notice	09/02/2008	73 FR 51302
Notice Comment Period End	11/03/2008	
No Further Action To Be Taken	11/25/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: State
Federalism: No

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Department of Health and Human Services (HHS)
Office of the Secretary (OS) RIN: 0991-AB53

View Related Documents

Title: Patient Safety and Quality Improvement Act of 2005; Civil Money Penalties Inflation Adjustment

Abstract: In accordance with the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, the rule will incorporate the penalty inflation adjustment for civil money penalties under the Patient Safety and Quality Improvement Act of 2005

Priority: Substantive, Nonsignificant
Agenda Stage of Rulemaking: Completed Action
Major: No
Unfunded Mandates: No
CFR Citation: 42 CFR 3.404 (To search for a specific CFR, visit the Code of Federal Regulations)
Legal Authority: 28 USC 2461 note Federal Civil Penalties Inflation Adjustment Act
Legal Deadline:

Action	Source	Description	Date
Other	Statutory		07/29/2009

Timetable:

Action	Date	FR Cite
Final Action	08/25/2009	74 FR 42777
Final Action Effective	11/23/2009	

Regulatory Flexibility Analysis Required: No
Government Levels Affected: No

Federalism: No

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